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

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[HYDROXYCHLOROQUINE,HYDROXYCHLOROQUINE SULFATE]			
Active Moiety:				
FDA Received Date:	From:	01-Mar-2020	To:	01-Oct-2020
MedDRA® Version* :	23.0			
Total Cases**:	12409			
Number of Pages:	8732			

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

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

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

U.S. FOOD & DRUG ADMINISTRATION

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	15624942	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557652-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Cyclical		Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Oral	Modified-Release Tablet		Not Reported
	Xeljanz			C				Not Reported
	Bupropion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	15674122	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573619-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling;	Humira			S	Subcutaneous			Not Reported

Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	16156564	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2731999-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	17223599	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015738		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Treatment Failure	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Hydro			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex

Leflunomide	S	Oral	Unk		Apotex
Hydroxychloroquine	S	Oral	Unk		Apotex
Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous	40 Mg, Unk (Once In Every Two Moths)		Not Reported
Humira	S	Unknown	20 Mg, Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	17480680	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06782			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; Off Label Use; Respiratory Arrest; Visual Impairment	Etanercept			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Oral	Unknown		Not Reported
	Celecoxib			S	Oral	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Subcutaneous	Unknown		Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Oral			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17009894	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2019479538			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Sepsis; Respiratory Failure; Septic Encephalopathy	No Subject Drug			S		No Dose Given		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S		1000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Erelzi			S	Unknown	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S		250 Mg, Unk		Not Reported
	Hydroxychloroquine			S		250 Mg, Unk		Not Reported

	Leflunomide	S	Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481109	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1193239		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Gastrointestinal Disorder; Headache; Nausea; Urinary Tract Infection	Prednisolone			S	Unknown	Initial Dose Not Stated		Actavis
	Prednisolone			S	Unknown	20 Milligram Daily; The Dose Was Tapered Further		Actavis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Cefradine	C	Unknown		Not Reported
	Amoxicillin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481183	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1070		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Arthralgia; Chills; Diarrhoea; Drug Ineffective; Fatigue; Heart Rate Increased; Liver Function Test Increased; Nausea; Ovarian Cyst; Ovulation Pain; Pain; Pyrexia; Quality Of Life Decreased; Rash; Uterine Cyst; Vomiting; Wheelchair User; White Blood Cell Count Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Benadryl			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481185	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1065		41 YR	Female	CAN

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

Gait Disturbance; Musculoskeletal Disorder; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481186	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481193	EXPEDITED (15-DAY)		OT	US-HETERO-HET2020US00241		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Oseltamivir			S	Unknown			Hetero
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555253		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482343	EXPEDITED (15-DAY)		DE, HO, OT	US-DRREDDYS-USA/USA/20/0120229		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse; Dyspnoea; Hypotension; Hypoxia; Pulmonary Oedema; Toxicity To Various Agents	Ibuprofen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482346	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482499	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020086129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Other	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483464	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1021060		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Warfarin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	High Dose		Not Reported
	Rivaroxaban			S	Unknown	Unk		Mylan
	Apixaban			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483713	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA054572			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Actemra	S	Unknown	Unk		Not Reported
Actemra	S				Not Reported
Anakinra	S	Unknown	Unk		Not Reported
Anakinra	S				Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483715	EXPEDITED (15-DAY)		LT	NVSC2020CA054458		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary	Ilaris			S	Subcutaneous	Unk (Single Use Vial)		Novartis
	Ilaris			S	Subcutaneous	Unk (Single Use Vial)		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk (Tablet)	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Endocervical	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk (Powder For Solution)	Not Reported
	Rituxan	S	Unknown	Unk (Solution Intravenous)	Not Reported
	Rituxan	S			Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483909	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA054590			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity;	Ilaris			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous	Unk, Solution		Not Reported

Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Anakinra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone	S	Unknown	10.0 Mg	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk, Solution Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Unk, 2 Every 1 Days	Not Reported
	Sulfasalazine	S	Unknown	500.0 Mg	Not Reported
	Xeljanz	S	Oral	Unk, 2 Every 1 Days	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17484491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559508		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Sulfate] Orencia	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485303	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06944		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485752	EXPEDITED (15-DAY)		OT	US-EMCURE PHARMACEUTICALS LTD-2020-EPL-000218			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus-Like Syndrome; Maternal Exposure During	Hydralazine Hydrochloride			S		10 Milligram Per Day		Heritage

Pregnancy	Hydralazine Hydrochloride	S	60 Milligram Per Day	Heritage
	Hydrochlorothiazide	S	Unk	Heritage
	Meloxicam	S	15 Milligram Daily	Heritage
	Meloxicam	S		Heritage
	Sulfasalazine	S	2 Gram, Bid	Heritage
	Sulfasalazine	S		Heritage
	Dicloxacillin	S	500 Milligram, Three Doses Over A 12-Hour Period	Not Reported
	Hydroxychloroquine	S	400 Milligram Per Day	Not Reported
	Hydroxychloroquine	S		Not Reported
	Prednisone	S	7.5 Milligram Daily	Not Reported
	Prednisone	S	20 Milligram Daily	Not Reported
	Naproxen	C	Daily	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485880	EXPEDITED (15-DAY)		OT	CA-CANTON LABORATORIES, LLC-2081207		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Naprosyn			S	Unknown			Canton Laboratories
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	16719246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892951-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17222231	EXPEDITED (15-DAY)		OT	GR-MYLANLABS-2019M1131972		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Mylan
	Exemestane			S	Unknown	Unk		Mylan
	Exemestane			S		Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Ramipril			S	Unknown	Unk		Mylan
	Ramipril			S	Unknown	Unk		Mylan
	Levothyroxine Sodium			S	Unknown	Unk		Mylan

Lansoprazole	S	Unknown	Unk		Mylan
Lansoprazole	S	Unknown	Unk		Mylan
Belimumab	S	Unknown	Unk		Mylan
Belimumab	S	Unknown	Unk		Mylan
Belimumab	S	Unknown	Unk		Mylan
Belimumab	S	Unknown	Unk		Mylan
Belimumab	S	Unknown	Unk		Mylan
Belimumab	S	Unknown	Unk		Mylan
Azathioprine	S	Unknown	Unk		Mylan
Azathioprine	S	Unknown	Unk		Mylan
Prednisolone	S	Unknown	Unk		Mylan
Prednisolone	S	Unknown	Unk		Mylan
Thyroxine	S	Unknown	Unk		Mylan
Thyroxine	S	Oral	Unk		Mylan
Hydroxychloroquine Sulfate	S	Unknown	Unk		Mylan
Dicumarol	C	Unknown	Unk		Mylan
Dicumarol	C	Unknown	Unk		Mylan
Dicumarol	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17226111	EXPEDITED (15-DAY)		OT	CA-INTERCEPT-PMOCA2018001237		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Alkaline Phosphatase Abnormal; Decreased Appetite; Fatigue; Gamma-Glutamyltransferase Increased; Malaise; Nausea; Therapy Interrupted; Weight	Ocaliva			S	Oral	5 Mg, Qd		Intercept Pharmaceuticals
	Ursodiol			S		750 Mg, Qd		Not Reported
	Ursodiol			S		750 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported

Decreased; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17466040	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555235			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17485751	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001128			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17485790	EXPEDITED (15-DAY)		OT	AU-ROCHE-2560432		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Xolair			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486058	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Form: Solution.		Not Reported
	Depo-Medrol			C	Other	Form: Suspension Intraarticular		Not Reported
	Depo-Medrol			C	Other			Not Reported

Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Diclofenac	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown	Tablet (Entericcoated)	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486321	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-006133			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk, Tablet		Concordia
	Arava			S	Oral	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Intra-articular	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486336	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201801-000172			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk Unk, Bid		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	25 Mg, Monthly (Q4w)		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S		25 Mg, Weekly		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Etanercept			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486441	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2558002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486453	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191742			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486497	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560384		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486594	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1128		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Losartan	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486971	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238900		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Hydroxychloroquine			S	Unknown			Sun
	Prednisolone			S	Unknown	60 Milligram		Taro
	Prednisolone			S				Taro
	Mycophenolate			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487663	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020089097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported
	Mycophenolate			S		1 G, 2x/Day		Not Reported
	Myfortic			S		Unk		Not Reported
	Prednisone			S		Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487715	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020092939			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea; Psoriasis	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487719	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020091248		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487720	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020093003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate Sodium			S		Unk, 1x/Day		Pfizer
	Anakinra			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Orencia			S				Not Reported

	Prednisone			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487793	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020091022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17495298	EXPEDITED (15-DAY)		DE, OT	US-FRESENIUS KABI-FK202002123		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolic Stroke; Endocarditis; Thrombocytopenia; Whipple'S Disease	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	14746343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009150		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Subcutaneous	Unk		Not Reported
	Risedronate			S	Unknown	Unk		Apotex

Disease; Malaise; Mass; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Risedronate	S	Oral	35 Mg, Q.Wk.	Apotex
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	22.5 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Novo-Rythro	S	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	200 Mg, Bid	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	4000 Iu, Qd	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Risedronate	C	Oral	35 Mg, Q.Wk.	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	300 Mg, Qd	Not Reported
	Bupropion	C	Unknown	300 Mg, Qd	Not Reported
	Cannabis Sativa	C	Unknown	Unk, Unknown	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15207176	EXPEDITED (15-DAY)		OT	PHHY2018GB052187		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Levothyroxine			S	Unknown	75 Mg, Qd		Not Reported
	Domperidone Maleate			S	Unknown	10 Mg, Tid		Not Reported
	Prednisolone Acetate			S	Unknown	7.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

Immunoglobulin I.V	S	Unknown	Unk		Not Reported
Creon	S	Unknown	10 Mg, Tid		Not Reported
Lansoprazole	S	Unknown	30 Mg, Qd		Not Reported
Uniphyllin	S	Unknown	200 Mg, Bid		Not Reported
Carbocisteine	S	Unknown	2 Df, Qd		Not Reported
Carbocisteine	S	Unknown	750 Mg, Bid		Not Reported
Risedronate	S	Unknown	35 Mg		Not Reported
Amylase	S	Unknown	10 Mg, Tid		Not Reported
Propanolol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15320874	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018341914		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Joint Warmth; Localised Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	16752576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2456918-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Joint Swelling; Knee Operation; Musculoskeletal Stiffness; Off Label Use; Product Use Issue; Psoriasis;	Humira 40mg/0.8ml			S	Subcutaneous	Frequency- Cyclical		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Salmeterol/Fluticason			C	Respiratory	250-50 Mcg		Not Reported

Therapeutic Product Effect Incomplete			(inhalation)			
	Levothyroxine Sodium	C	Oral			Not Reported
	Alprazolam	C	Oral	Prn		Not Reported
	Prednisone	C				Not Reported
	Celebrex	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17395555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007224		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Q.H.		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk, Cyclical		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qid		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Q.H.		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Q.Wk.		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk, Cyclical		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not	8 Df, Unk		Not Reported

		otherwise specified)		
Actemra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	300 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk, Cyclical	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Oral	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17484448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559662		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell	Rituximab			S	Unknown			Not Reported

Carcinoma; Diarrhoea; Renal Mass; Vomiting	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Medroxyprogesterone Acetate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Anakinra	C		Not Reported
	Cyclosporine	C	Unknown	Not Reported
	Depo-Provera	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17490734	EXPEDITED (15-DAY)		OT	IT-LAURUS LABS LIMITED-202000070		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome; Off Label Use	Hydroxychloroquine			S	Unknown			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560163		60 YR	Female	CAN

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

Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491499	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

Tenosynovitis; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491509	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491554	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560158		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491788	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1166			Female	CAN

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

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)	S	Other	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559690		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492138	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559679		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492506	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Disease Carrier; Depressed Mood; Emotional Distress; Exostosis; Labelled Drug-Drug Interaction Medication Error; Pleural Effusion; Pleural Thickening; Pneumothorax; Rheumatoid Arthritis; Rib Fracture	Naproxen Sodium			S	Oral	500 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492547	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202002000969			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492862	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Haemoglobin Decreased; Musculoskeletal Disorder; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493033	EXPEDITED (15-DAY)		HO	CA-ROCHE-2555409		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Naproxen	C		Not Reported
	Plaquenil Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493052	EXPEDITED (15-DAY)		DS	CA-ROCHE-2560161		48 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493140	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560157			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493887	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1192504		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17494074	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2020-US-1193378		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Drug Ineffective; Overdose; Pulmonary Oedema; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	6 G Missing		Not Reported
	Ibuprofen			S	Oral			Actavis
	Epinephrine			S	Unknown			Teva
	Naproxen			S	Oral			Teva
	Potassium			S	Unknown			Actavis
	Norepinephrine			S	Unknown			Teva
	Sodium Bicarbonate			S	Unknown	Drips		Not Reported
	Calcium			S	Unknown			Not Reported
	Dextrose-50			S	Unknown			Not Reported
	Vasopressin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17494702	EXPEDITED (15-DAY)		DE, OT	IN-APPCO PHARMA LLC-2081256		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Death; Nocardiosis; Septic Shock; Shunt Infection	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17497976	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-016630		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17498115	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17498463	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported

Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form- Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular	Dosage Form- Suspension Intra-Articular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	13950566	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-080121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Oral		Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	15635243	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105931			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Off Label Use; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	160 Milligram		Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Imuran [Azathioprine Sodium]			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	15814007	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2018375765			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Chronic Obstructive Pulmonary Disease; Haemorrhoids; Mucosal Inflammation; Rheumatoid Arthritis; Transaminases Increased; Weight Decreased	No Subject Drug			S		No Dose Given		Not Reported
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Unk, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Unk, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Leflunomide			S		10 Mg, Unk		Not Reported
	Leflunomide			S		10 Unk, Unk		Not Reported
	Leflunomide			S		10 Mg, Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Roactemra			S		162 Mg, Unk		Not Reported
	Erelzi [Etanercept]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	7412801	EXPEDITED (15-DAY)		OT	TR-SANOFI-AVENTIS-2010SA030554		57 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Visual Acuity Reduced; Visual Impairment	Hydroxychloroquine			S	Unknown	200 Mg,Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17498943	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238987		62 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499155	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3300813-00		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective; Multimorbidity; Off Label Use; Product Use Issue; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499291	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-005903			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	50 Die		Not Reported
	Azathioprine			C		Unk		Not Reported
	Imuran			C		Unk		Not Reported

Methotrexate	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499294	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1188			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499295	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1187			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial	Rituxan			S	Intravenous (not			Not Reported

Lung Disease; Joint Swelling; Treatment Failure			otherwise specified)		
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499478	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000125			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Weekly, (Qow)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly (Q4w)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Monthly, Powder And Solution For Solution For Injection		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Myocrisin			S	Unknown	Unk		Not Reported
	Arava			C		20 Mg, Qd		Not Reported
	Arava			C		Unk		Not Reported
	Ativan			C				Not Reported

	Dilaudid	C	Not Reported
	Enablex	C	Not Reported
	Lasix	C	Not Reported
	Loperamide	C	Not Reported
	Norflex	C	Not Reported
	Omnaris	C	Not Reported
	Pantoloc	C	Not Reported
	Synthroid	C	Not Reported
	Vagifem	C	Not Reported
	Abatacept	C	Not Reported
	Rituxan	C	Not Reported
	Kineret	C	Not Reported
	Benadryl Allergy	C	Not Reported
	Cortisone	C	Not Reported
	Desoximetasone	C	Not Reported
	Diphenhydramine	C	Not Reported
	Plantago Ovata	C	Not Reported
	Actemra	C	Not Reported
	Sodium Aurothiomalate	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499831	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001191			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Haemorrhage	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Erelzi			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500720	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559521		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis;	Rituxan			S	Intravenous drip			Not Reported

Treatment Failure	Anakinra	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500766	EXPEDITED (15-DAY)		OT	US-ZYDUS-048013		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema; Macule; Pain Of Skin; Skin Plaque; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Azathioprine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501274	EXPEDITED (15-DAY)		DE, LT, OT	US-STRIDES ARCOLAB LIMITED-2020SP002142		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Crying; Dyspnoea; Hypotension; Oxygen Saturation Decreased; Pulmonary Oedema; Pupil Fixed; Salivary Hypersecretion	Ibuprofen			S	Oral	Unk, (Tablets)		Strides
	Naproxen			S	Oral	Unk, (Tablets)		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501565	NON-EXPEDITED			US-PFIZER INC-2020097824		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Phenobarbital			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501605	NON-EXPEDITED			US-PFIZER INC-2020097853		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Phenobarbital			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17504725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1193099		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17504736	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1193102		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Bacillus Calmetteguerin Bcg			C	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	14767196	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018049244		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16284325	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019016961		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Unk		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S				Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		20 Milligram		Not Reported
	Methotrexate			S		10 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported

Prednisone	C		10 Milligram		Not Reported
Sulfasalazine	S				Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16519993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017276980		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16600153	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068088		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Diclofenac	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Plaquenil S	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16838640	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-27173			Female	CAN

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

	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Arava	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17142317	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2019051903		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin	Cimzia			S	Subcutaneous	Solution		Not Reported
	Alendronate Sodium			S		70 Milligram, 4x/Week		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apremilast			S		60 Milligram, 2x/Day (Bid)		Not Reported
	Apremilast			S		Unk		Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Infliximab			S	Oral	Unk		Not Reported

Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S		70 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		12 Milligram, 4x/Week	Not Reported
	Methotrexate	S		17.5 Milligram, 4x/Week	Not Reported
	Methotrexate	S		10 Milligram, 4x/Week	Not Reported
	Methotrexate	S		15 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		12.5 Milligram, 4x/Week	Not Reported
	Motrin [Ibuprofen]	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Once Daily (Qd)	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S			Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S			Not Reported
	Otezla	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2x/Day (Bid)	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Stelara	S	Subcutaneous	Solution	Not Reported
	Sulfasalazine	S	Endocervical	Unk	Not Reported
	Tocilizumab	S		360 Milligram	Not Reported
	Tocilizumab	S		680 Milligram	Not Reported
	Enbrel	S		25 Milligram, 2x/Week	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C			Not Reported
	Colchicine	C		Unk	Not Reported
	Dexilant	C			Not Reported
	Febuxostat	C			Not Reported

	Folic Acid	C			Not Reported
	Gravol	C	Unk		Not Reported
	Mogadon	C			Not Reported
	Nitrazepam	C			Not Reported
	Oxycodone	C			Not Reported
	Prednisone	C	Unk		Not Reported
	Uloric	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17370536	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2020047226		51 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection	Sulfasalazine			S		Unk		Pfizer
	Trexan [Methotrexate]			S		Unk		Pfizer
	Oxiklorin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17405600	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000668			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyspepsia; Eczema; Nodule; Psoriatic Arthropathy; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Otezla			S	Oral	60 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17456605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007874		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Joint Swelling;	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Meloxicam			S	Unknown	15 Mg, Unk		Apotex

Rheumatoid Arthritis	Humira	S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium	C	Unknown	20 Mg, Unk		Not Reported
	Budesonide W/Formoterol Fumarate	C	Unknown	Unk		Not Reported
	Gabapentin	C	Unknown	100 Mg, Unk		Not Reported
	Lansoprazole	C	Unknown	30 Mg, Unk		Not Reported
	Plaquenil /00072602/	C	Unknown	Unk		Not Reported
	Plaquenil /00072602/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17505326	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000222			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Dysgeusia; Fluid Retention; Lower Respiratory Tract Infection; Musculoskeletal Pain; Pain In Extremity	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Folic Acid			S	Unknown	1 Mg, Qd		Not Reported
	Meloxicam			S	Unknown	15 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17506038	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1207			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea; Psoriasis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17507539	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-175043		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction; Off Label Use	Methotrexate			S	Subcutaneous			Accord
	Dolquine			S	Oral	Strength: 200 Mg, 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17508707	EXPEDITED (15-DAY)		HO, OT	IT-IPCA LABORATORIES LIMITED-IPC-2020-IT-000811			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563624		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Imuran [Azathioprine]	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509657	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1023932		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Mylan
	Celecoxib			C	Unknown			Mylan
	Cyclobenzaprine			C	Unknown			Mylan
	Immunoglobulin /07494701/			C	Intravenous (not otherwise specified)			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509914	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06905		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported

Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17510338	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197076		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17511324	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198114		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514071	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563594		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563684		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563709		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514081	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514088	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514090	EXPEDITED (15-DAY)		DS	CA-ROCHE-2563708		48 YR	Female	CAN

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

Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Solution Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Unknown	Solution	Not Reported
	Bupropion		C			Not Reported
	Esomeprazole		C			Not Reported
	Folic Acid		C			Not Reported
	Levothyroxine		C			Not Reported
	Naproxen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514110	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564021		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563829		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant;	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Rheumatoid Arthritis; Thyroid Neoplasm	Enbrel		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2020	17511813	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-010743			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Thrombotic Stroke; Transient Ischaemic Attack	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	13053105	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870952		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Imuran [Azathioprine]	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15332459	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176746		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	16858320	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-SHIRE-SK201931249			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Maternal Exposure During Pregnancy; Oligohydramnios; Premature Baby	Human Normal Immunoglobulin			S	Transplacental	Unk		Shire
	Human Normal Immunoglobulin			S				Shire
	Hydrocortisone			S	Transplacental	Unk		Not Reported
	Hydrocortisone			S				Not Reported
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Vitamin K Nos			S				Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Bisulepin			S				Not Reported
	Nadroparine			S	Transplacental	Unk		Not Reported
	Nadroparine			S				Not Reported
	Etamsylate			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental			Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]			S	Transplacental	Unk		Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]			S				Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Metoprolol Tartrate			S	Transplacental	Unk		Not Reported
	Metoprolol Tartrate			S				Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S				Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Vitamin B Complex			S	Transplacental	Unk		Not Reported
	Vitamin B Complex			S				Not Reported

Albumin	S	Transplacental	Unk	Not Reported
Albumin	S			Not Reported
Paracetamol	S	Transplacental	Unk	Not Reported
Paracetamol	S			Not Reported
Folic Acid	S	Transplacental	Unk	Not Reported
Folic Acid	S			Not Reported
Methylprednisolone Sodium Succinate	S	Transplacental	Unk	Not Reported
Methylprednisolone Sodium Succinate	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S			Not Reported
Dicynon	S	Transplacental	Unk	Not Reported
Dicynon	S			Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Cefixime	S			Not Reported
Vitamin D [Colecalciferol]	S	Transplacental	Unk	Not Reported
Vitamin D [Colecalciferol]	S			Not Reported
Ornidazole	S	Transplacental	Unk	Not Reported
Ornidazole	S			Not Reported
Omeprazole	S	Transplacental	Unk	Not Reported
Omeprazole	S			Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S			Not Reported
Fluconazole	S	Transplacental	Unk	Not Reported
Fluconazole	S			Not Reported
Magnesium Lactate	S	Transplacental	Unk	Not Reported
Magnesium Lactate	S			Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S			Not Reported
Vulmizolin	S	Transplacental	Unk	Not Reported
Vulmizolin	S			Not Reported

	Aminomethylbenzoic Acid	S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid	S				Not Reported
	Hydroxychloroquine	S	Transplacental	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17462267	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002000962			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug-Induced Liver Injury; Hepatic Steatosis; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17514982	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197337		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17514985	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515012	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197749		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515017	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197995		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis;	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Estrogel		C	Unknown	1.8 Percent Daily;	Not Reported
	Furosemide		C	Unknown		Not Reported
	Morphine		C	Unknown		Not Reported
	Potassium Chloride		C	Unknown	1500 Milligram Daily;	Not Reported
	Valsartan		C	Unknown	320 Milligram Daily;	Not Reported
	Xalatan		C	Ophthalmic	50 Microgram Daily;	Not Reported
	Zingiber Officinale		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515026	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197604		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515117	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197685		54 YR	Female	CAN

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

Injection Site Reaction; Meningitis; Rheumatoid Arthritis	Methotrexate	S	Unknown	Barr
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563785		54 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515200	EXPEDITED (15-DAY)		OT	GB-MICRO LABS LIMITED-ML2020-00579		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Atorvastatin			S				Micro Labs
	Apixaban			S				Micro Labs

	Rivaroxaban	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Clopidogrel	S		Not Reported
	Warfarin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515331	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197063		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous	2 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515947	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2020SP003312		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram, Unknown		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17516183	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020100139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S				Pfizer
	Arava			S				Not Reported
	Humira			S		Once Weekly		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17516870	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517057	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243755		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Interstitial Lung Disease; Treatment Failure	Stelara			S	Subcutaneous	4.0 Years		Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Mercaptopurine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Pamidronate Disodium	S	Unknown		Not Reported
	Tenoxicam	S	Unknown		Not Reported
	Xeljanz	S	Unknown	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517125	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517277	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001247			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17518881	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198199		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Losartan			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17518920	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001368			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519921	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519967	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001365			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519980	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001364			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519984	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001363			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519985	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001362			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519989	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001367			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519991	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001366			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519999	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001369			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17520010	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001371			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17520013	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001370			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16085204	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05925		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknwon Solution Subcutaneous		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported

	Simponi	S	Subcutaneous	Unknown	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16838864	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27398		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported

	Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported
	Cephalexin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518377	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559714			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518870	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001248			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518875	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2 Every 2 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Celebrex			C	Oral	200 Milligram, Bid		Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518935	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564545		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported

Apo-Azathioprine	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Azathioprine	S	Unknown			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Gold	S	Intramuscular			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Imuran [Azathioprine]	S	Unknown			Not Reported
Imuran [Azathioprine]	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518982	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519028	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001249			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519034	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197395		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Methotrexate	S	Oral	20 Milligram Daily;		Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519069	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001250			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519160	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001398			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519161	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001397			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519188	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001393			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519189	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001392			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519200	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001394			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519203	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519483	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001381			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519484	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001380			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519489	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001379			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519490	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001389			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519495	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001383			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519498	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001382			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported

	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Loperamide	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Plantago Ovata	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Vagifem	C	Vaginal	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519544	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001252			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Concordia
	Prednisone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519545	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001253			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pleural Effusion; Pneumonia	Hydroxychloroquine			S	Transplacental	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519551	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001254			Unknown	USA

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

Foetal Exposure During Pregnancy; Rectal Haemorrhage	Hydroxychloroquine		S	Transplacental	Unk	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519651	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1196061		30 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Micofenolato De Mofetilo (7330lm)			S	Oral	500 Mg 12 Hours		Teva
	Colchimax (Colchicine/Dicycloverine Hydrochloride)			S	Oral	0.5 Mg 24 Hours		Not Reported
	Dolquine 200 Mg Comprimidos, 30 Comprimidos			S	Oral	200 Mg 12 Hours		Not Reported
	Rituximab (2814a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519653	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197404			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519654	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198000			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519660	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198122			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Dermatitis Allergic; Hepatic Cirrhosis; Hypersensitivity; Psoriasis; Rash Papular; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	400 Milligram Daily;		Barr
	Hydroxychloroquine			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfanilamide			S	Unknown			Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519699	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519737	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug	Etanercept			S	Unknown	Unknown		Not Reported

Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Actemra	S	Unknown	Unknown		Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Unknown,		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unknown		Not Reported
	Naproxen	C	Unknown	Unknown		Not Reported
	Risedronate Sodium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519854	EXPEDITED (15-DAY)		OT	NVSC2020CA064906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Neoral			S	Oral	20 Mg		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Plaquenil			S	Oral	20 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521788	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130309		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder;	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported

Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Sulfasalazine	S	Unknown			Not Reported
	Leflunomide	S	Oral	20 Mg, Qd		Sanofi
	Cimzia	S	Subcutaneous			Not Reported
	Cosentyx	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S		Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Desvenlafaxine Succinate	C				Not Reported
	Prednisone	C				Not Reported
	Quetiapine Fumarate	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521819	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020103635		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Off Label Use; Product Use Issue; Skin Reaction; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	Unk, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17522043	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020101975		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide	Enbrel			S	Subcutaneous	Unk		Pfizer

Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
	Apo-Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	25 Mg, 1x/Day	Not Reported
	Apo-Prednisone	S	Oral	3 Mg, 1x/Day	Not Reported
	Arava	S	Unknown	20 Mg, 1x/Day	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold Radioactive Colloidal	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Indomethacin	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	3 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	50 Mg, Weekly	Not Reported
	Prednisone	S	Oral	25 Mg, 1x/Day	Not Reported
	Prednisone	S		50 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not	Unk	Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous	Unk		Not Reported
	Cymbalta	C	Unknown	30 Mg, 1x/Day		Not Reported
	Folic Acid	C	Oral	Unk Unk, Weekly		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524186	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1198464			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524188	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198197		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea; Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198573			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524518	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198591		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gadolinium-Zeolite Xanthan Gum Complex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram Daily;		Not Reported
	Humira			C	Unknown			Not Reported

Hydroxychloroquine Sulfate	C	Unknown			Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram Daily;		Not Reported
Prednisone	C	Unknown	5 Milligram Daily;		Not Reported
Sulfasalazine	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526220	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07630		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use	Infliximab			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Prednisone	S	Unknown			Not Reported
	Rituximab	S	Unknown	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Xeljanz	S	Oral			Not Reported
	Gabapentin	C	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Cetirizine Hydrochloride	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526909	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526918	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198570			Female	CAN

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

	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	14747168	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098040		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Erythromycin			S	Unknown	Unk, Unk		Sanofi
	Erythromycin			S	Unknown	Unk		Sanofi
	Risedronate Sodium			S	Oral	35 Mg, Qw		Not Reported
	Methotrexate			S	Oral	22.5 Mg,Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400.0 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S		Unk, Unk		Not Reported
	Marijuana			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	300 Mg, Qd		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Ergocalciferol			C	Unknown	4000.0 Iu, Qd		Not Reported
	Bupropion			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	15350172	EXPEDITED (15-DAY)		OT	CA-ROCHE-2179240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17434256	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002000843			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Cholestatic; Pneumonia; Rash; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Hydroxychloroquine			S		Unk		Concordia
	Azathioprine			S		Unk		Not Reported
	Oseltamivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17448695	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP007808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Localised Infection; Skin Discolouration; Skin Exfoliation; Soft Tissue Necrosis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Intramuscular	80 Mg, Unk		Not Reported
	Sulfasalazine			C	Oral	1500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17485746	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-			Unknown	CAN

202002001107

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Oral	200 Mg, Qd (1 And 1/2 Tablets), Tablet		Concordia
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk, On And Off		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17498908	EXPEDITED (15-DAY)		DE, HO	NVSC2020US060102		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Trametinib			S	Oral	2 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17523978	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198588		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug	Methotrexate			S	Unknown			Barr

Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra		S	Unknown	Not Reported
	Anakinra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Simponi		S	Unknown	Not Reported
	Desoximetasone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17523994	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020101881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Methotrexate Sodium			S	Subcutaneous	20 Mg, Once Weekly		Pfizer
	Actemra			S		300 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		300 Mg, 1x/Day		Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous	1 Every 2 Months		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17524962	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529355	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198780		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198768		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Malaise; Night Sweats; Peripheral Swelling; Vomiting	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529557	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1199245		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Methotrexate			S	Unknown			Barr

Humira	S	Subcutaneous	200 Milligram Daily;		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Atrovent	C				Not Reported
Benztropine Mesylate	C				Not Reported
Chlordiazepoxide	C				Not Reported
Folic Acid	C				Not Reported
Levomepromazine Maleate	C				Not Reported
Methotrexate	C				Not Reported
Pantoprazole	C				Not Reported
Risedronate Sodium	C				Not Reported
Salbutamol	C				Not Reported
Trifluoperazine [Trifluoperazine Hydrochloride]]	C				Not Reported
Zopiclone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529613	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1199352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Indometacin			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199350		56 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Methotrexate	S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate	S	Oral	40 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529653	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198795		69 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529761	EXPEDITED (15-DAY)		OT	NVSC2020CA065255		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg (Solution)		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk (Solution)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg/Kg		Not Reported

Plaquenil	S	Unknown	Unk		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk (Solution)		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw (1 Every 1 Weeks)		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529893	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2020-0010681		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529928	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2020-0010695		62 YR	Female	CAN

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

Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Morphine Sulfate	S	Unknown	Unk		Purdue
	Arava	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	25 Mg, Weekly		Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid		Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17530605	EXPEDITED (15-DAY)		DE, HO, OT	CA-PFIZER INC-2020105703		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Odynophagia; Rash; Rash Vesicular; Skin Lesion; Thrombocytopenia; Varicella Zoster Virus Infection	Methotrexate Sodium			S	Unknown	2.5 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	10 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17532248	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Folic Acid	C	Oral	2.5 Milligram, Qd		Not Reported
Methotrexate	C	Oral	10 Milligram, Qwk		Not Reported
Methotrexate	C	Oral	15 Milligram, Qwk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd		Not Reported
Tenofovir Disoproxil	C	Unknown	Unk		Not Reported
Tenofovir Disoproxil	C	Unknown	300 Milligram		Not Reported
Xeljanz	C	Unknown			Not Reported
Zopiclone	C	Unknown	7.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	10592296	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2014089242		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S				Amgen
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qd		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	14 Milligram, Qd		Not Reported

Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk Unk, Bid	Not Reported
	Prednisone	S	Unknown	14 Milligram, Qd	Not Reported
	Dilaudid	C	Unknown	4 Milligram, Tid	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Furosemide	C	Unknown	Unk, Qd	Not Reported
	Hydromorph Contin	C	Unknown	18 Milligram, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11512274	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015094557		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Rituxan			S	Unknown	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not	1000 Milligram		Not Reported

					otherwise specified)					
	Simponi			C	Unknown	Unk				Not Reported
	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12316477	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054049			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2000 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Folic Acid			S	Unknown	1 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12430947	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014016405		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Bronchitis; C-Reactive Protein	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen

Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Plaquenil	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methadone	S	Unknown	Unk	Not Reported
	Rampril	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, Bid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported

	Vitamin D	C		10000 Unit, Qwk	Not Reported
	Gravol Ginger	C		500 Milligram, As Needed	Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Estrogel	C		0.6 Percent, Tid	Not Reported
	Estrogel	C	Unknown	1 Dosage Form, Qd	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	13890626	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP016769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Apo-Meloxicam			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Amitriptyline			S	Unknown	Unk		Apotex
	Mobicox			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Enbrel			S	Unknown	500 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

	Pantoprazole		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	14872540	EXPEDITED (15-DAY)		OT	PHHY2018CA005549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15207382	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Arava			S	Oral	10 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 3 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 1 Every 2 Days		Not Reported

Arava	S	Oral	10 Mg, Qd 3 Months	Not Reported
Arava	S	Oral	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Unk	Not Reported
Arava	S	Unknown	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Q3wk	Not Reported
Arava	S	Unknown	10 Mg, Qd	Not Reported
Arava	S	Oral	10 Mg, Bid	Not Reported
Arava	S	Oral	10 Mg, Q3mo	Not Reported
Arava	S	Unknown	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Mg, Qd	Not Reported
Methotrexate Sodium	S	Unknown	Unk 2 Year	Not Reported
Methotrexate Sodium	S	Intramuscular	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Intramuscular	Unk	Not Reported

	Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
	Methotrexate	S	Intramuscular	12.5 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk Unk, 1 Every 2 Years	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15415981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187426		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	16697992	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2884328-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug-Induced Liver Injury	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17395700	EXPEDITED (15-DAY)		OT	NVSC2020CN032994		26 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Placenta Praevia; Premature Delivery; Systemic Lupus Erythematosus; Therapy Non-Responder	Prednisone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk (3 Day Shock Therapy)		Not Reported
	Alfacalcidol			S	Unknown	Unk		Not Reported
	Vita-D			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17449475	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188488		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Condition Aggravated; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported

Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naprosyn E	S	Unknown	1000 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous	17.8571 Milligram Daily;	Not Reported
	Orencia	S	Sunconjunctival		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Methotrexate	S	Subcutaneous		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Lovastatin	C	Unknown		Not Reported
	Metoprolol	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen Sodium	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Rosuvastatin	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17488215	EXPEDITED (15-DAY)		OT	NVSC2020CA054557			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17528339	EXPEDITED (15-DAY)		OT	GB-ABBVIE-20K-167-3311302-00			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dactylitis; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Hypoaesthesia; Joint Injury; Joint Swelling; Joint Swelling; Nausea; Paraesthesia; Psoriatic Arthropathy; Rash; Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral	10mg To 15mg		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Intramuscular			Not Reported
	Cosentyx			S	Oral			Not Reported

	Abatacept	C	Subcutaneous		Not Reported
	Tocilizumab	C	Subcutaneous		Not Reported
	Leflunomide	C			Not Reported
	Leflunomide	C			Not Reported
	Leflunomide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17528689	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565797		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566099			Female	CAN

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

	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529273	EXPEDITED (15-DAY)		DE	US-TEVA-2020-US-1196969		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Teva
	Celecoxib			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529304	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198615			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported

	Tylenol Arthritis Pain 8h			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529403	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1199756		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529425	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199839		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529432	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199813		62 YR	Male	CAN

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

Nephrolithiasis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529848	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199821			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529855	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1310			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530810	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067074		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis;	Neoral			S	Unknown	Unk		Novartis

Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate		S	Unknown	Unk	Not Reported
	Celebrex		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Imuran		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566092		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17532826	NON-EXPEDITED			US-PFIZER INC-2020106873		70 YR	Female	USA

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

Drug Hypersensitivity	Cytotec	S	Unk	Pfizer
	Prevacid	S	Unk	Not Reported
	Cyclosporine	S	Unk	Not Reported
	Zelnorm	S	Unk	Not Reported
	Amitiza	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Reglan	S	Unk	Not Reported
	Maxzide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533105	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA126625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Prednisone			S	Oral	5 Mg,Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Domperidone			C	Oral	10 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533202	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020105885			Female	CAN

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Methotrexate Sodium	S		20 Mg, Weekly		Pfizer
	Arava	S				Not Reported
	Diclofenac	S				Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Arthrotec	C				Not Reported
	Desoximetasone	C				Not Reported
	Ibuprofen	C				Not Reported
	Naproxen	C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral			Not Reported
	Prednisone	C	Oral	Unk, 1x/Day		Not Reported
	Sulfasalazine	C				Not Reported
	Synthroid	C		Unk, 1x/Day		Not Reported
	Tramadol	C	Oral	Unk, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533357	EXPEDITED (15-DAY)		OT	NVSC2020CN068678		57 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia; Product Use In Unapproved Indication	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S				Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533406	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020101939		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling;	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 3x/Day		Pfizer

Pulmonary Mass	Hydroxychloroquine	S		700 Mg, 1x/Day	Not Reported
	Kevzara	S		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Vitamin D [Ergocalciferol]	C		Unk	Not Reported
	Candesartan	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534005	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1198666		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Intravenous (not otherwise specified)			Not Reported

	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534213	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1200643			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534440	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1200638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown	18.9 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534762	EXPEDITED (15-DAY)		OT	CA-PURDUE-CAN-2020-0010680		70 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17535515	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199872			Female	CAN

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

Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17535606	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1200575			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	11493051	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015093019		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis;	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

Swelling; Therapeutic Product Effect Decreased	Sulfasalazine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12982514	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016166769		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk (4 Years)		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Coversyl			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Cephalexine			C	Unknown	500 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13857420	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017119578		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Foot Operation; Ill-Defined Disorder; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	300 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Cyclical		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1.0 Dosage Form, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S	Intravenous drip	1 Gram		Not Reported
	Actonel			S	Unknown	35 Milligram, Qwk		Not Reported

Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	20 Milligram, Qd		Not Reported
Leflunomide	S	Unknown	1.0 Dosage Form		Not Reported
Risedronate	S	Unknown	Unk		Not Reported
Risedronate	S	Unknown	35 Milligram, Qwk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14551816	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022286		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14680239	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018039685		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Cyclosporine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Kevzara	S	Unknown	20 Mg, Unk (Every 14 Days For Eight Weeks)	Not Reported
	Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Esomeprazole Sodium	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	20 Milligram	Not Reported
	Sarilumab	S	Subcutaneous	20 Milligram, Q2wk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Nicotinamide	S	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Act Esomeprazole	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Adalimumab	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	400 Mg, Qd	Not Reported
	Nexium	C	Unknown	Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Magnesium	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported

Dexpanthenol	C	Unk		Not Reported
Riboflavin	C	Unk		Not Reported
Vitamin A [Retinol]	C	Unk		Not Reported
Vitamin C [Ascorbic Acid]	C	Unk		Not Reported
Esomeprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14767128	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018049251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15227464	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016244288			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	Unk 2 Year		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

Methotrexate Sodium	S	Intramuscular	Unk	Pfizer
Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Unk	Pfizer
Methotrexate Sodium	S	Unknown	12.5 Mg, Unk	Pfizer
Methotrexate Sodium	S	Subcutaneous	40 Mg, Unk	Pfizer
Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Qwk	Pfizer
Methotrexate Sodium	S	Intramuscular	12.5 Mg, Qd	Pfizer
Methotrexate Sodium	S	Unknown	12.5 Mg, Qwk	Pfizer
Methotrexate Sodium	S	Unknown	Unk Unk, 1 Every 2 Years	Pfizer
Methotrexate Sodium	S	Unknown	Unk	Pfizer
Arava	S	Oral	10 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, 3 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, 1 Every 2 Days	Not Reported
Arava	S	Oral	10 Mg, Qd 3 Months	Not Reported
Arava	S	Oral	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Unk	Not Reported
Arava	S	Unknown	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Q3wk	Not Reported
Arava	S	Unknown	10 Mg, 1x/Day	Not Reported
Arava	S	Oral	10 Mg, Bid	Not Reported
Arava	S	Oral	10 Mg, Q3mo	Not Reported
Arava	S	Unknown	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not	200 Mg, Unk	Not Reported

			otherwise specified)		
	Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15552704	EXPEDITED (15-DAY)		OT	PHHY2018CA041941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported
	Methotrexate			C	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15702406	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016089441		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	17.5 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Qwk		Not Reported

Methotrexate	C	Unknown	17.5 Milligram		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	15 Milligram, Qwk		Not Reported
Methotrexate	C	Subcutaneous	17.5 Milligram, Qwk		Not Reported
Sulfasalazine	C	Oral	1 Gram, Qd		Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid		Not Reported
Depo-Medrol	C		Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17205119	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353124		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Leflunomide			S		25 Mg, Qw		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Arava			S		25 Mg, Qw		Sanofi
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17448568	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007862		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Hydroxychloroquine			S	Unknown	Unk		Apotex

Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Apo-Leflunomide		S	Unknown	Unk	Apotex
	Leflunomide		S	Unknown	Unk	Apotex
	Celebrex		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Salazopyrin		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17450389	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007813		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apremilast			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Penicillin /00000901/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567108		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535341	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566061		75 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566158			Female	CAN

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

Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab		S	Unknown	Not Reported
	Etanercept		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Levothyroxine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535690	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Vision Blurred	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535822	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1201117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535930	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold Radioactive Colloidal			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536008	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201159		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Off Label Use; Product Use	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

Issue; Somnolence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536095	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201014		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536102	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cartilage Injury; Depression; Dizziness; Drug Ineffective; Grip Strength Decreased; Lethargy; Malaise; Nausea; Night Sweats; Palpitations; Panic Attack; Renal Function Test Abnormal; Tremor	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Diclofenac			C				Not Reported
	Diclofenac			C	Oral			Not Reported
	Diclofenac			C	Oral			Not Reported
	Diclofenac			C				Not Reported

	Sulfasalazine	C		2 Gram Daily;	Not Reported
	Tamsulosin Hydrochloride	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536155	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201165		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Rash; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536157	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201155			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536347	EXPEDITED (15-DAY)		DS	CA-ROCHE-2567157		46 YR	Female	CAN

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

Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536389	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-012470		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Atorvastatin			S	Unknown	High Dose		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Apixaban			S	Intracardiac	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536668	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536746	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020039826		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Subcutaneous	Unk		Amgen

Arava	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536862	EXPEDITED (15-DAY)		OT	NVSC2020CA065750		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Oral	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Cyclosporine			S	Unknown			Novartis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Chloroquine			S	Subcutaneous			Not Reported

Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Unk		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Plaquenil	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral			Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Xeljanz Xr	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566115		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536988	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001464			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Pain	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537638	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566129		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Off Label Use; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537665	EXPEDITED (15-DAY)		OT	NVSC2020CA071564			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Bid (2 Every 1 Days)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537726	EXPEDITED (15-DAY)		OT	NVSC2020CN068677		49 YR	Female	CHN

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

Autoimmune Haemolytic Anaemia; Product Use In Unapproved Indication	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab	S				Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk		Novartis
	Mycophenolate Mofetil	S				Novartis
	Cyclosporine	S	Unknown	Unk		Not Reported
	Cyclosporine	S				Not Reported
	Tacrolimus	S	Unknown	Unk		Not Reported
	Tacrolimus	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17539658	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201177			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17540077	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067086		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single-Use)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17540780	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201306		57 YR	Female	CAN

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

Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Methotrexate	S	Unknown	25 Mg, 1 Every 1 Week	Barr
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Rituximab	S	Unknown		Not Reported
	Actemra	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17541043	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Norflex /00018303/	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc /01263204/	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	16968290	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2979286-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Aleve			C		Frequency-As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17541781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565716			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17541831	EXPEDITED (15-DAY)		HO	CA-ROCHE-2566096			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	16867027	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2944310-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	17542644	NON-EXPEDITED		HO	CA-AMGEN-CANSP2020042344		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12301979	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014315082		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Celebrex			S		200 Mg, 2x/Day (Bid)		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Unk, Daily (Qd)		Pfizer
	Methotrexate Sodium			S				Pfizer
	Arava			S		Unk		Not Reported
	Arava			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Monthly		Not Reported
	Actemra			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Apo-Prednisone			S		14 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 2x/Day		Not Reported
	Prednisone			S	Unknown	14 Mg, 1x/Day		Not Reported
	Dilaudid			C		4 Mg, 3x/Day		Not Reported
	Dilaudid			C				Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Furosemide			C		Unk, 1x/Day		Not Reported
	Hydromorph Contin			C		18 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12416801	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016278196		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Celebrex	S		Unk	Pfizer
	Infliximab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	1 Dose	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Methadone	S		Unk	Not Reported
	Rampril	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
	Estrogel	C	Unknown	1.0 Df Qd	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, 2x/Day	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported

	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Weekly	Not Reported
	Jampk20	C		1500 Mg, 1x/Day	Not Reported
	Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
	Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
	Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
	Baclofen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13033547	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-095488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported

	Sulfasalazine		S	Unknown	Unk	Not Reported
	Meloxicam		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13862390	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017119633		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported
	Erythromycin			C		Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13908900	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017128230		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelera			S	Subcutaneous	Unk		Not Reported
	Stelera			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Myochrysine			S	Parenteral	Unk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Myochrysine			S	Subcutaneous	Unk		Not Reported

Myochrysine	S	Unknown	Unk	Not Reported
Otezla	S	Oral	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Sirukumab	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Minocin	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	250 Milligram, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Rheumatrex	C		Unk	Not Reported

	Prednisone		C	Unknown	5 Milligram	Not Reported
	Abatacept		C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13909421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127635		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single Use Prefilled Syringe)		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Imuran	C	Unknown	Unk		Not Reported
Arthrotec	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Ergocalciferol	C		Unk		Not Reported
Azathioprine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14156261	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017164983			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1.0 Dosage Form, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	10 Milligram, Qd		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk Unk, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Citalopram Hydrobromide			C	Unknown	40 Milligram, Qd		Not Reported
	Citalopram Hydrobromide W/Mirtazapine			C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14186410	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170220			Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Enbrel	S	Unknown	25 Milligram, Q2wk	Amgen
	Enbrel	S	Unknown	25 Milligram, Qwk	Amgen
	Enbrel	S	Unknown	25 Milligram	Amgen
	Enbrel	S	Unknown	25 Milligram, Cyclical	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk (Solution Subcutaneous)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk (Solution Subcutaneous)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Oral	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk, (Powder For Solution Intravenous)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Cyclical	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qwk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Oral	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14562748	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018073659		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	2 Gram, Qd		Pfizer
	Apo-Prednisone			S	Unknown	5 Milligram, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14623298	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031822		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Tofacitinib	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported
Prednisone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14775658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018157923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15209356	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018101357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Unk, Unk (Three In One Week)		Not Reported
	Hydroxychloroquine			S	Unknown	200 Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15416427	EXPEDITED (15-DAY)		OT	PHHY2018CA102776		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off	Neoral			S	Oral	Unk		Novartis

Label Use; Treatment Failure	Neoral	S	Subcutaneous	Injection	Novartis
	Cyclosporine	S	Subcutaneous	Unk	Novartis
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxyquinoline Sulfate	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Xeljanz	C	Unknown	2 Ot, Qd	Not Reported
	Xeljanz	C	Oral	10 Mg, Qd	Not Reported

	Xeljanz			C	Unknown	2 Df, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15577112	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2541011-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	579		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15629800	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558453-00		60 YR	Female	CAN

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

Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Inflammation; Joint Range Of Motion Decreased; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acidophilus	C		Not Reported
	Aspirin	C		Not Reported
	Calcium	C		Not Reported
	Deflazacort	C		Not Reported
	Dilaudid	C		Not Reported
	Ergocalciferol	C		Not Reported
	Hydromorphone Hydrochloride	C	Intramuscular	Not Reported
	Januvia	C		Not Reported
	Kenalog	C	Intra-articular	Not Reported
	Lidocaine	C	Topical	Not Reported
	Metronidazole	C		Not Reported
	Nitroglycerin	C		Not Reported
	Pantoloc	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Risedronate	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Salbutamol	C		Not Reported
	Triamcinolone	C		Not Reported
	Tylenol	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Triamcinolone Acetonide	C		Not Reported
	Salicylic Acid	C		Not Reported

	Rosuvastatin	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15687047	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018170659		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Orencia			S	Oral	200 Milligram, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15700850	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018119653		49 YR	Female	CAN

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

Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Enbrel	S		Unk	Pfizer
	Sulfasalazine	S		Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, Bid	Pfizer
	Adalimumab	S	Unknown	Unk	Not Reported
	Act Esomeprazole	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Esomeprazole Sodium	S	Unknown	Unk	Not Reported
	Folic Acid	S		Unk	Not Reported
	Nicotinamide	S		Unk	Not Reported
	Azathioprine	S		Unk	Not Reported
	Thiamine Hydrochloride	S		Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Qwk, Six Months	Not Reported
	Kevzara	S		20 Mg, Unk (Every 14 Days For Eight Weeks)	Not Reported
	Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
	Sarilumab	S	Subcutaneous	20 Mg, 2x/Week	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Riboflavin	C		Unk	Not Reported
	Vitamin A [Retinol]	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
	Dexpanthenol	C		Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
	Nexium [Esomeprazole Magnesium]	C	Unknown	Unk	Not Reported
	Esomeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15924554	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653465-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine[Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16140862	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083231		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg		Not Reported
	Orencia			S				Not Reported
	Rituxan			S		Solution Intra Venous		Not Reported
	Salazopyrin			S				Not Reported
	Actemra			C				Not Reported
	Bifidumbacterin			C				Not Reported
	Celebrex			C				Not Reported
	Loperamide			C				Not Reported
	Methotrexate			C				Not Reported
	Pantoprazole			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16181416	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2738191-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16291815	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087638			Unknown	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Aleve	S	Unknown	Unk	Bayer
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Kineret	S	Subcutaneous	50.0 Mg, Qd	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	5.0 Mg, Bid	Not Reported
	Enbrel	S	Subcutaneous	25.0 Mg, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 4iw	Not Reported
	Enbrel	S	Subcutaneous	25 Unk	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70.0 G	Not Reported
	Hydroxychloroquine	S	Oral	5.0 Mg, Qd	Not Reported
	Infliximab	S	Unknown	5.0 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg, Ow	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg, Ow	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250.0 Mg, Q1mon	Not Reported
	Prednisone	S	Oral	3.0 Mg, Bid	Not Reported
	Prednisone	S	Oral	5.0 Unk	Not Reported
	Sulfasalazine	S	Oral	250.0 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280.0 Mg, Q2wk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Ow	Not Reported
	Triamcinolone	S	Subcutaneous	25.0 Mg, Q2wk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Gamastan	S		70.0 G	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5.0 Mg/Kg, Qd	Not Reported

	Naproxen	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Immunoglobulin I.V	S	Intravenous (not otherwise specified)	70.0 G	Not Reported
	Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16797341	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019146895		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk Unk, Qwk		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C	Unknown	Unk Unk, Bid		Not Reported
	Estrogel			C		0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C		320 Milligram, Qd		Not Reported
	Xalatan			C		50 Microgram, Qd		Not Reported
	Zingiber Officinale			C	Oral	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16948402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972424-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17427584	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1186381		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptosporidiosis Infection; Hypogammaglobulinaemia ; Leukopenia; Neutropenia; Weight Decreased	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449016	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007838		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Deformity; Gastrointestinal Disorder; Loss Of Personal Independence In Daily	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Parenteral	15 Mg, Unk		Not Reported
	Methotrexate			S	Parenteral	25 Mg, Unk		Not Reported

Activities; Nausea	Sulfasalazine	S	Unknown	Unk, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Aleve			C	Unknown	Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Sulfasalazine			C	Oral	2000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542948	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566947			Female	CAN

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

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542960	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566909		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dequalinium Chloride			C				Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

Tylenol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543200	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543233	EXPEDITED (15-DAY)		DE, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1339		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Syndrome; Odynophagia; Product Use Issue; Rash; Rash Vesicular; Skin Lesion; Thrombocytopenia; Varicella Zoster Virus Infection	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543244	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543246	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1323		66 YR	Male	CAN

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

Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Candesartan	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543431	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201880			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Fatigue; Feeling Abnormal; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Cefazolin			C	Unknown			Not Reported
	Clindamycin			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Tylenol W/Codeine No. 3			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543733	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202183		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543737	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202308		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543813	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Methotrexate			S	Unknown			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Apo-Diclofenac			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543832	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201901			Female	CAN

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

Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate		S	Unknown	Barr
	Humira		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544307	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020899		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Q4wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544337	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567702		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544346	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567710		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported

Arthritis; Stomatitis	Doxycycline		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Tylenol 8 Hr Arthritis Pain		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544665	NON-EXPEDITED			US-PFIZER INC-2020112039		26 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544958	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1026331		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy;	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Unknown

Oligohydramnios; Premature Baby	Cefotaxime	S	Unknown	Unk	Mylan
	Cefotaxime	S		Unk	Mylan
	Privigen	S	Unknown	Unk	Mylan
	Privigen	S		Unk	Mylan
	Prednisone	S	Unknown	Unk	Mylan
	Methylprednisolone	S	Unknown	Unk	Mylan
	Dexamethasone	S		Unk	Mylan
	Dexamethasone	S	Unknown	Unk	Mylan
	Vitamin B Complex /04259401/	S	Unknown	Unk	Mylan
	Cefixime	S	Unknown	Unk	Mylan
	Metoprolol Tartrate	S	Unknown	Unk	Mylan
	Bisoprolol Fumarate	S	Unknown	Unk	Mylan
	Penicillin G /00000903/	S	Unknown	Unk	Mylan
	Vulmizolin	S	Unknown	Unk	Mylan
	Bisulepin	S	Unknown	Unk	Mylan
	Ornidazole	S	Unknown	Unk	Mylan
	Albumin	S	Unknown	Unk	Mylan
	Aminomethylbenzoic Acid	S	Unknown	Unk	Mylan
	Magnesium Lactate	S	Unknown	Unk	Mylan
	Folic Acid	S	Unknown	Unk	Mylan
	Nadroparin Calcium	S	Unknown	Unk	Mylan
	Hydroxychloroquine	S	Unknown	Unk	Mylan
	Vitamin D /00318501/	S	Unknown	Unk	Mylan
	Hydrocortisone	S	Unknown	Unk	Mylan
	Etamsylate	S	Unknown	Unk	Mylan
	Flebogamma Dif /00025201/	S	Unknown	Unk	Mylan
	Fluconazole	S	Unknown	Unk	Mylan
	Potassium Chloride	S	Unknown	Unk	Mylan
	Paracetamol	S	Unknown	Unk	Mylan

	Vitamin K Nos		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544990	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166761		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Adverse Drug Reaction; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Orencia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Qw		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Adalimumab			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg,Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg,Qw		Not Reported
	Methotrexate			C	Unknown	17 Mg		Not Reported
	Methotrexate			C	Unknown	15 Mg, Qw		Not Reported

Methotrexate	C	Subcutaneous	25 Mg, Qw		Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Qw		Not Reported
Sulfasalazine	C	Oral	1 G,Qd		Not Reported
Xeljanz	C	Oral	5 Mg,Bid		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Depo-Medrol	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544993	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA210576		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Arava			S	Oral	10 Mg,Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk,Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S		Unk Unk,Unk		Sanofi
	Methotrexate			S		20 Mg, Qw, Solution		Not Reported
	Methotrexate			S	Unknown	12.5 Df,Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg		Sanofi
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Orencia			S	Subcutaneous	25 Mg		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported
	Rituxan	S		Unk	Not Reported
	Gold	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Actemra	S			Not Reported
	Actemra	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
	Prednisone	C	Unknown	40 Mg, For 3 Years	Not Reported
	Prednisone	C	Unknown	250 Mg, For 7 Months	Not Reported
	Bifidobacterium Bifidum	C			Not Reported
	Celebrex	C			Not Reported
	Loperamide	C			Not Reported
	Sulfasalazine	C			Not Reported
	Pantoprazole	C			Not Reported
	Xeljanz	C	Oral	5 Mg	Not Reported
	Simponi	C			Not Reported
	Wellbutrin	C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545370	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020112214			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Xeljanz			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545594	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130822		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Headache; Joint Swelling; Pain In Jaw; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Meloxicam			S		15 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C		20 Mg		Not Reported
	Symbicort			C		Unk		Not Reported
	Gabapentin			C		100 Mg		Not Reported
	Lansoprazole			C		30 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546119	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1198500			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Haemorrhage	Hydroxychloroquine Sulfate Teva			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546196	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020111601		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis	Torvast			S				Pfizer

Superficial	Paracetamol Alter		S	Oral	1 G, 1x/Day	Not Reported
	Xarelto		S	Oral	20 Mg, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546249	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA069998		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Oxycodone			S	Unknown	10 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S				Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Cannabis Sativa			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S			Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Rituximab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546340	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3318751-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo Azathioprine			S	Unknown			Not Reported
	Apo Leflunomide			S	Oral			Not Reported
	Apo Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Azathioprine	S	Unknown	Not Reported
Azathioprine	S		Not Reported
Celebrex	S	Unknown	Not Reported
Celebrex	S		Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S		Not Reported
Cimzia	S	Subcutaneous	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C		Not Reported
Codeine Phosphate	C		Not Reported
Altace	C		Not Reported
Apo Gabapentin	C	Oral	Not Reported
Atorvastatin Calcium	C		Not Reported
Escitalopram	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Conjugated Estrogens	C		Not Reported
Cymbalta	C		Not Reported
Escitalopram	C		Not Reported
Estrace	C		Not Reported
Gabapentin	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Hydromorphone Hcl	C		Not Reported
Mupirocin	C	Topical	Not Reported
Pantoprazole	C		Not Reported
Shark Liver Oil	C		Not Reported
Tapentadol Hydrochloride	C		Not Reported

	Taro Mupirocin	C	Topical	Not Reported
	Tramacet	C	Oral	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021288		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546844	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202539		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Methotrexate			S	Unknown			Barr
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546910	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202524		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C				Not Reported
	Lozide			C				Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	11624328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1476711-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthritis; Blood	Humira			S	Subcutaneous			Not Reported

Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Anakinra	C		Not Reported
	Ativan	C		Not Reported
	Benadryl	C		Not Reported
	Cortisone	C	Intramuscular	Not Reported
	Cortisone	C	Intra-arterial	Not Reported
	Dilaudid	C		Not Reported
	Enablex	C		Not Reported
	Lasix	C		Not Reported
	Leflunomide	C		Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C	Spray, Metered Dose	Not Reported
	Pantoprazole Sodium	C		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Vagifem	C	Vaginal	Not Reported
	Synthroid	C		Not Reported
	Abatacept	C		Not Reported
	Desoximetasone	C	Intra-arterial	Not Reported
	Darifenacin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12933730	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA201530		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Arava			S	Oral	10 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	500 Mg,Bid		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	20 Mg,Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			S		Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 G,Qcy		Not Reported
	Rituxan			S		2 Unk, Qcy		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2 G, Q6m		Not Reported

	Etanercept	S	50 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13519996	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2444		55 YR	Female	CAN

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

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869342	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017351180		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported
	Erythromycin			C		Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13921480	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372781		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Prefilled Syringe)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid (1 Every 12 Hours)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Leflunomide	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Imuran	C	Unknown	Unk		Not Reported
	Arthrotec	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Azathioprine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14570743	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0535		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cystitis; Deformity; Depressed Mood; Encephalitis; Encephalitis Brain Stem; Fibromyalgia; Immunosuppression; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Peripheral Swelling; Product Use Issue; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Seizure; Sepsis; Spinal Deformity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14632418	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020711		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown	70 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	680 Mg, Qmo		Not Reported
	Tocilizumab			S	Unknown	360 Mg, Qmo		Not Reported

Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Leflunomide	S	Unknown		Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ciclosporin	S	Unknown	150 Milligram, Qd	Not Reported
Xeljanz	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15215485	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018305256		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q2wk		Not Reported

	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, 2x/Week	Not Reported
	Hydroxychloroquine	S	Unknown	400 Unk, Unk (Three In One Week)	Not Reported
	Leflunomide	S		Unk	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15357865	EXPEDITED (15-DAY)		HO	PHHY2018DK086994		47 YR	Female	DNK

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15383851	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported

Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Milligram, Qmo	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Milligram, Qwk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	420 Milligram	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous	15 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15617576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555631-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Site Reaction	Plaquenil	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Leflunomide	C		Not Reported
	Meloxicam	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619319	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554744-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lipitor			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619584	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2555197-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide Apotex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported

Swelling; Rheumatoid Arthritis; Wheelchair User	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15620413	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555889-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15627588	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2559128-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Pain; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Plaquenil			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Risedronate			C	Oral			Not Reported
	Arava			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15660935	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016545757		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S		4 Years		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Prednisone			C		10 Mg, 1x/Day		Not Reported
	Coversyl [Perindopril Erbumine]			C		Unk		Not Reported
	Hydroxychloroquine			C				Not Reported
	Cephalexine			C	Unknown	500 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15710031	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015280551		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Leflunomide	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15720388	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017364037		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, Bid		Pfizer
	Minocin			S	Unknown	Unk		Pfizer
	Minocycline Hcl			S	Unknown	Unk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Ustekinumab	S	Unknown	Unk	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Abatacept	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15926889	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651972-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Tablet		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16075583	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012946		14 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Intentional Product Use Issue; Lymphoproliferative Disorder; Off Label Use; Off Label Use Of Device; Product Use In Unapproved Indication; Renal Cell Carcinoma	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Metformin Tablet			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Ferrous Fumarate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	100.0 Milligram, 1 Every 1 Month		Not Reported
	Infliximab			S	Unknown	1000.0 Milligram, 1 Every 1 Month		Not Reported
	Infliximab			S				Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Nutropin			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Not Reported
	Sulfamethoxazole			S	Unknown	Unk		Not Reported
	Androderm			S	Unknown	Unk		Not Reported
	Protropin			S	Intramuscular	Unk		Not Reported
	Acetazolamide			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported

Cyclosporine	S	Unknown	Unk		Not Reported
Cyclosporine	S				Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S				Not Reported
Insulin Human	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16332181	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019210438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Estradot			S	Transdermal	Unk, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16334554	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018103158		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram		Pfizer

	Methotrexate Sodium	S	Unknown	20 Milligram	Pfizer
	Tofacitinib Citrate	S	Unknown	Unk	Pfizer
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, (1 Every 2 Week(S))	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported
	Prednisone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16600726	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb

Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	50 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk Unk, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Cutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16691316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2885135-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16802106	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396164		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis;	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Leflunomide		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Ergocalciferol		C		Unk, Weekly	Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate		C		Unk, 2x/Day	Not Reported
	Estrogel		C		0.6 %, 3x/Day	Not Reported
	Furosemide		C		40 Mg, 1x/Day	Not Reported
	Morphine		C	Unknown	Unk	Not Reported
	Potassium Chloride		C	Unknown	1500 Mg, 1x/Day	Not Reported
	Valsartan		C		320 Mg, 1x/Day	Not Reported
	Xalatan		C		50 Ug, 1x/Day	Not Reported
	Zingiber Officinale		C	Oral	500 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16830577	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547396	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-059951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use;	Cefixime			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo

Product Use In Unapproved Indication	Bisoprolol	S	Unknown	Unk	Not Reported
	Imuran	S	Oral	100 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Morphine	S	Unknown	Unk	Not Reported
	Nifedipine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rivotril	S	Unknown	Unk	Not Reported
	Zantac	S	Unknown	Unk	Not Reported
	Zopiclone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547563	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001263			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Bifidobacterium Bifidum			C		Unk		Not Reported
	Align			C		Unk		Not Reported
	Actemra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547716	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001646			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Tablet		Concordia
	Silver			S	Oral	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported

Penicillin G Sodium	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Weekly		Not Reported
Desoximetasone	C		Unk		Not Reported
Hydroxychloroquine	C		Unk		Not Reported
Tofacitinib Citrate	C		Unk		Not Reported
Tylenol [Paracetamol]	C		Unk		Not Reported
Cortisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547762	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001274			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral	Unk		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Erythromycin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Subcutaneous Solution		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Weekly		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Novo-Rythro			S	Unknown	Unk		Not Reported
	Risedronate Sodium			S	Oral	35 Mg, Weekly		Not Reported
	Marijuana			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023061		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1391			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548364	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548444	EXPEDITED (15-DAY)		OT	NVSC2020CA073084		63 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral	S	Subcutaneous	Unk	Novartis
	Neoral	S	Oral	Unk	Novartis
	Cyclosporine	S	Unknown	Unk	Novartis
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	1 Df, Qw	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548451	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567814		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Kevzara			C	Unknown			Not Reported
	Neurontin			C	Unknown	1800 Milligram Daily;		Not Reported
	Premarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548476	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203253			Female	CAN

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

Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate	S	Unknown	2.8571 Milligram Daily;	Barr
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Calcium	C			Not Reported
	Fentanyl	C			Not Reported
	Folic Acid	C			Not Reported
	Magnesium	C			Not Reported
	Naproxen Sodium	C			Not Reported
	Pantoprazole	C			Not Reported
	Potassium	C			Not Reported
	Tramadol	C			Not Reported
	Vitamin D[Colecalciferol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548477	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203601		67 YR	Female	CAN

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

	Valsartan	C	320 Milligram Daily;		Not Reported
	Zingiber Officinale	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548712	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203265			Female	CAN

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

Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Methotrexate	S	Unknown		Barr
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Tylenol Arthritis Pain 8h	C			Not Reported
	Desoximetasone	C		20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203616		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548868	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Increased	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204060		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549539	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR042663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Product Use Issue; Toxicity To Various Agents	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549774	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-012083		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome; Neutrophilia; Whipple'S Disease	Methylprednisolone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclobenzaprine			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550494	NON-EXPEDITED			NVSC2020US075268		21 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550624	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			C	Unknown	500 Milligram, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550986	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08585		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood	Infliximab			S	Intravenous (not			Not Reported

Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure			otherwise specified)		
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous, Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution, Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Unknown, Solution, Subcutaneous	Not Reported

Plaquenil	S	Unknown	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Piroxicam	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551371	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551480	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023095		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551711	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021350		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown	0.8 Milliliter		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552311	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021309		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204244		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552337	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1204372		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Discitis; Pyrexia; Synovitis; Transaminases Increased	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552354	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203747			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552356	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204264			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552357	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204242		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552382	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1204376		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3324326-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Decreased	Xeljanz	S	Oral		Not Reported
	Haemophilus Influenzae	C		Vaccine	Not Reported
	Prevnar 13	C	Intramuscular		Not Reported
	Tetanus Vaccine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552708	EXPEDITED (15-DAY)		OT	NVSC2020CA073106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported

Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Humira	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552911	EXPEDITED (15-DAY)		OT	NVSC2020CA071955		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Humira	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	20 Mg		Not Reported
Methotrexate	S	Oral	20 Unk		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Remicade	S	Unknown	3 Mg		Not Reported
Sulphasalazine	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17553141	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027175			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Milligram, Qd For 3 Months		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13856372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qd		Not Reported

	Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14447073	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043369		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Arava			S	Oral	Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk Unk,Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Benzylpenicillin Sodium			S	Unknown	Unk Unk, Unk		Not Reported
	Phenoxymethylpenicillin Potassium			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
Gold	S	Unknown	Unk Unk, Unk		Not Reported
Rituximab	S		Unk		Not Reported
Prednisone	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14570820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0542		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14788664	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15243408	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0441		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Cosentyx	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Ramipril	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Estrogel	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Xalatan	C	Unknown	Not Reported
Cosopt	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Vitamin D	C	Unknown	Not Reported
Jampk20	C	Unknown	Not Reported
Dorzolamide Hcl/Timolol Maleate	C	Unknown	Not Reported
Baclofen	C	Unknown	Not Reported
Levaquin	C	Unknown	Not Reported
Potassium Chloride	C	Unknown	Not Reported
Zingiber Officinale	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Estradiol	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15293692	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		55 YR	Male	CAN

PHARMA-TREX2016-1469

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15621032	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557288-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Oxycodone			S	Unknown	Cr Tablet		Not Reported
	Enbrel			S	Unknown			Not Reported

Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actemra	C		Not Reported
	Enbrel	C		Not Reported
	Leflunomide	C		Not Reported
	Lyrica	C	Oral	Not Reported
	Oxycodone	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15624172	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556726-00		57 YR	Male	CAN

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

	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15721414	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1025		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Loss Of Personal Independence In Daily Activities; Nodule; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16075451	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012895		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week(S)		Aurobindo
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 1 Every 2 Week(S)		Not Reported
	Humira			S	Unknown	40 Milligram, 1 Every 1 Week(S)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram, 1 Every 1 Week(S)		Not Reported
	Orencia			S	Unknown	78 Milligram, 1 Every 1 Week(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1000 Milligram, 2 Every 1day(S)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 1month(S)		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every 1month(S)		Not Reported

Methotrexate	S	Subcutaneous	10 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	50 Milligram, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	780 Milligram, Once A Day	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every Week (S)	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16205757	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020198		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness;	Amlodipine Tablets			S	Oral	Unk, 1 Every 1 Day		Aurobindo
	Amlodipine Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
	Asacol			S	Unknown	800 Milligram, 3 Every 1 Day		Not Reported
	Asacol			S	Unknown	800 Milligram, 3 Every 2 Day		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Gliclazide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Ebastine	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16206143	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome;	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported

Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16387694	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029951		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month(S)		Not Reported
	Actemra			S	Unknown	680 Milligram, Once A Day, 1 Every 1 Month(S)		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week(S)		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Week(S)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	10.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram, Every		Not Reported

				Week	
	Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50.0 Milligram, 1 Every 1 Month(S)	Not Reported
	Myochrysine	S			Not Reported
	Orencia	S	Unknown	780.0 Milligram, Every Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram, Two Times A Day	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10.0 Milligram, Daily	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16440716	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822523-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain;	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Peripheral Swelling; Rheumatoid Arthritis	Methotrexate		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16729866	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2896155-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16758967	EXPEDITED (15-DAY)		OT	PHHY2019CA200445			Female	CAN

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

Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Lopresor	S	Unknown	Unk	Novartis
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Codeine Phosphate	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qd	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Penicillin	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxyquinoline Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16820448	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3439		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17001941	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2989075-00		83 YR	Female	USA

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

Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Fentanyl	S	Unknown	Not Reported
	Levothyroxin	C		Not Reported
	Raloxifene	C		Not Reported
	Lidoderm	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17099946	EXPEDITED (15-DAY)		HO, OT	CA-COVIS PHARMA B.V.-2019COV00285		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic	Alvesco			S	Respiratory (inhalation)	200 Mg, 1x/Day		Covis
	Omnaris			S	Nasal	50 Mg, Unk		Covis
	Pantoloc			S		40 Mg, Unk		Not Reported
	Ivermectin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Prednisone			S		50 Mg, Unk		Not Reported
	Salbutamol Sulfate			S		100 Mg, Unk		Not Reported
	Umeclidinium Bromide			S		62.5 Mg, Unk		Not Reported
	Zenhale			S		Unk, 2x/Day		Not Reported
	Sulfasalazine			C				Not Reported
	Arava			C				Not Reported

Product Effect Incomplete;
Underweight; Vasculitis;
Weight Decreased;
Wheezing

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17523584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17526969	EXPEDITED (15-DAY)		HO	DE-CELLTRION INC.-2020DE020115			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus;	Rituximab (Unknown)			S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported

Urinary Tract Infection	Methotrexate	S	Unknown	7.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	2.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	2.5 Mg, Unk	Not Reported
	Mabthera	S	Unknown	500 Mg, Unk	Not Reported
	Mabthera	S	Unknown	500 Mg, Unk	Not Reported
	Mabthera	S	Unknown	500 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17543429	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2497274-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553452	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001630			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Arava			S	Oral	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Domperidone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553454	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001673			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567770			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205022		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554157	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1205088			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554179	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205203			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Moxifloxacin Hydrochloride			S	Oral			Teva
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554197	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tofacitinib		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Rabeprazole Sodium		C	Oral	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C				Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554209	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020112925		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug	Enbrel			S	Unknown	50 Milligram		Pfizer

Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Milligram	Pfizer
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	500 Milligram, Tid	Not Reported
	Naproxen	S	Unknown	500 Milligram, Tid	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Tramadol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554234	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205191		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554424	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1205198		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554632	EXPEDITED (15-DAY)		OT	NVSC2020CA072976		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Plaquenil			S	Oral	20 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not	8 Mg/Kg		Not Reported

				otherwise specified)		
	Enbrel		S	Subcutaneous	50 Mg 1 Every 1 Weeks	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565792		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565710			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Sulfasalazine	S	Oral	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555043	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565721		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567695		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568898		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555514	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1412		40 YR	Female	CAN

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

Abdominal Distension; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Minocin	S	Unknown	Not Reported
	Minocycline Hcl	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Ustekinumab	S	Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Myochrysine	S	Subcutaneous	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Stelara	S	Unknown	Not Reported

Stelara	S	Subcutaneous	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apremilast	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported
Abatacept	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555803	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027221		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Prednisone			S		25 Mg, Qd		Not Reported
	Prednisone			S		(7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S		15 Mg, Qd		Not Reported
	Prednisone			S		Unk (25 Mg Qd, Dose Tapering)		Not Reported

	Prednisone	S	(15 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unk Unk (12.5 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unk Unk (10 Mg Qd, Dose Tapering)	Not Reported
	Tacrolimus	S	Unk Unk, Qd	Not Reported
	Mycophenolate Mofetil	S	Unk Unk, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	400 Mg, Qd	Mylan
	Methylprednisolone	C	Unk (Pulses)	Mylan
	Rituximab	C	Unk	Mylan
	Immunoglobulin I.V	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020114584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17556462	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1027359			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Abatacept			S	Unknown	Unk		Mylan

	Roactemra	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557419	NON-EXPEDITED			NVSC2020US076875		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Tacrolimus			S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557715	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown	250 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Hydrocortisone Valerate			C	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Lyderm			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sodium Aurothiomalate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557720	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205274		38 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557806	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Headache;	Methotrexate			S	Subcutaneous			Barr

Influenza Like Illness; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Rheumatoid Arthritis; Weight Fluctuation	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Actemra	C				Not Reported
	Actemra	C				Not Reported
	Enbrel	C	Subcutaneous	50 Milligram Daily;		Not Reported
	Humira	C	Subcutaneous			Not Reported
	Orencia	C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17558048	NON-EXPEDITED		OT	NVSC2020US076308		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Gait Inability; Herpes Zoster; Rash; Skin Necrosis	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13516429	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Kineret	S	Subcutaneous			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Anakinra	S	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13929206	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2675		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Imuran	C	Unknown	Not Reported
Arthrotec	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14223269	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021499			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported

Enbrel	S	Unknown	50 Mg, Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Imuran /00001501/	S	Unknown	Unk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14727278	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2018JPN056741		45 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Cytomegalovirus Infection; Neutrophil Count Decreased; Pancreatitis Acute; Pneumocystis Jirovecii Pneumonia; White Blood Cell Count Decreased; White Blood Cell Count Decreased	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Two Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, 1d		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg		Glaxosmithkline
	Furosemide			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	70 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	60 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	50 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	40 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Intravenous drip	40 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Intravenous drip	60 Mg, 1d		Glaxosmithkline

Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	30 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	22.5 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	20 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	60 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	35 Mg, 1d	Glaxosmithkline
Prograf	S	Oral	Unk	Not Reported
Cellcept	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Meropenem	S	Intravenous drip	1 G, Tid	Not Reported
Meropenem	S	Intravenous drip	Unk	Not Reported
Miraclid	S	Intravenous drip	300000 Iu, 1d	Not Reported
Omeprazole	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
Solu Medrol	C	Intravenous (not otherwise specified)	1000 Mg, 1d	Not Reported
Solu Medrol	C	Intravenous (not otherwise specified)	125 Mg, 1d	Not Reported
Valixa	C		Unk	Not Reported
Bonalon	C		Unk	Not Reported
Novorapid	C		Unk	Not Reported
Baktar	C		1 Df, We	Not Reported
Baktar	C			Not Reported
Daikenchuto	C		Unk	Not Reported
Sodium Picosulfate Hydrate	C		Unk	Not Reported
Tenelia	C		Unk	Not Reported
Pitavastatin Calcium	C		Unk	Not Reported

	Cardenalin	C	Unk	Not Reported
	Rabeprazole Sodium	C	Unk	Not Reported
	Azilva	C	Unk	Not Reported
	Amlodipine Besilate	C	Unk	Not Reported
	Azelnidipine	C	Unk	Not Reported
	Carvedilol	C	Unk	Not Reported
	Bayaspirin	C	Unk	Not Reported
	Sennoside	C	Unk	Not Reported
	Insulin Glargine (Genetical Recombination)	C	Unk	Not Reported
	Spironolactone	C	Unk	Not Reported
	Humalog	C	Unk	Not Reported
	Persantin-L	C	Unk	Not Reported
	Feburic	C	Unk	Not Reported
	Bonviva	C	Unk	Not Reported
	Novolin R	C	Unk	Not Reported
	Trazenta	C	Unk	Not Reported
	Polaprezinc	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15207582	NON-EXPEDITED			US-PFIZER INC-2018300600		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15605753	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3227		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

	Sarilumab	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15675159	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2495		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Coversyl			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

	Cephalexine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15962909	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013651		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoarthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	200 Milligram, 2 Every 1 Day		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16082171	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06027		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis;	Infliximab			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported

Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Acidophilus	C	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Deflazacort	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Januvia	C	Unknown	Unknown	Not Reported
	Lidocaine	C	Topical		Not Reported
	Metronidazole	C	Unknown	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Unknkown	Not Reported
	Pantoloc	C	Unknown	Unknown	Not Reported
	Pregabalin	C	Unknown		Not Reported
	Pregabalin	C			Not Reported
	Pregabalin	C			Not Reported
	Risedronate	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported
	Salbutamol	C	Unknown	Unknown	Not Reported
	Salicylic Acid/Triamcinolone Acetonide	C	Intra-articular		Not Reported

Triamcinolone	C	Unknown			Not Reported
Tylenol	C	Unknown	Unknown		Not Reported
Xeljanz	C	Oral			Not Reported
Calcium Gluconate	C	Unknown	Unknown		Not Reported
Lactobacillus Acidophilus	C	Unknown	Unknown		Not Reported
Risedronate Sodium	C	Unknown	Unknown		Not Reported
Salicylic Acid	C	Unknown	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular	Suspension, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16444894	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033815		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin			S	Unknown	Unk		Aurobindo
	Metformin			S				Aurobindo
	Cymbalta			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Coumadin			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported
	Imuran			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16866958	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-092201		36 YR	Female	CAN

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

Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Abatacept	S	Unknown		Bristol Myers Squibb
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Mefenamic Acid	S	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17390832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0682		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Methotrexate (Trade Name			S	Unknown			Not Reported

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Unknown)				
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tylenol	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17397400	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA032774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557868	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013437		53 YR	Female	CAN

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

Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Celecoxib Capsules	S	Unknown	Unk	Aurobindo
	Celecoxib Capsules	S			Aurobindo
	Anakinra	S	Unknown	100 Milligram	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram, Once A Day	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Apo-Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S			Not Reported
	Celebrex	S	Unknown	200 Milligram	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	1 Milliliter, Every Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, 1 Every 1 Month	Not Reported
	Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once A Day	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 1 Month	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Altace	C	Unknown	5 Milligram	Not Reported
	Altace	C	Unknown	10 Milligram	Not Reported

Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C	Unknown	300 Milligram	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Once A Day	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram, Once A Day	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	0.625 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	20 Milligram	Not Reported
Cymbalta	C	Unknown	30 Milligram, Four Times/Day	Not Reported
Cymbalta	C	Unknown	60 Milligram	Not Reported
Cymbalta	C	Unknown	120 Milligram, Once A Day	Not Reported
Cipralex	C	Unknown	20 Milligram	Not Reported
Escitalopram	C	Unknown	10 Milligram	Not Reported
Estrace	C	Unknown	0.5 Milligram	Not Reported
Gabapentin	C	Oral	100 Milligram	Not Reported
Gabapentin	C	Unknown	3000 Milligram	Not Reported
Hydrochlorothiazide	C	Unknown	12.5 Milligram	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Milligram, Two Times A Day	Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Milligram, Two Times A Day	Not Reported
Mupirocin	C	Topical	Unk	Not Reported
Pantoloc	C	Intravenous (not otherwise specified)	20 Milligram, Once A Day	Not Reported
Shark Liver Oil	C	Unknown	Unk	Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Milligram	Not Reported
Taro-Mupirocin	C	Topical	Unk	Not Reported
Tramacet	C	Oral	Unk	Not Reported
Tramadol Hydrochloride	C	Oral	50 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557974	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558021	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201711-006521			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	200 Mg, Bid, Tablet		Concordia
	Apo-Folic			S	Unknown	1 Dosage Form, Biw(Twice A Week)		Not Reported
	Apo-Gabapentin			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 4 Times In A Week		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558061	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013432		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10.0 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400.0 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5.0 Milligram		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20.0 Milligram, Once A Day		Not Reported
	Methotrexate			S	Oral	25.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400.0 Milligram, Once A Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000.0 Milligram, Two Times A Day	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	50.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558697	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Cetrizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558984	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201806-002196			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash Maculo-Papular; Toxic Skin Eruption; Vitreous Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	100 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod (Film-Coated Tablet)		Concordia
	Onetram			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Prorenal			C		Unk		Not Reported
	Seroquel			C		Unk		Not Reported
	Magnesium Oxide			C		Unk		Not Reported
	Cefalexin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559013	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08978		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Treatment Failure	Etanercept	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Imuran	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559017	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08970		51 YR	Female	CAN

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

Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Etanercept	S	Unknown	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Imuran	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Parenteral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Parenteral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Arava	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Tofacitinib	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569481		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559217	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568742			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565794		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559517	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568861		89 YR	Male	CAN

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

	Naprosyn [Naproxen]	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559606	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2081773		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559853	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021632		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559980	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021788		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566109			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559994	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021821			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560048	EXPEDITED (15-DAY)		OT	GB-ACCORD-176336		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin/Atorvastatin Calcium			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown			Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2020-021912

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560261	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202003001629			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia; Hangnail; Nail Avulsion; Onychoclasis; Sjogren'S Syndrome; Stomatitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Resumption		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560263	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003001668			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg		Concordia
	Nivaquine			C		100 Mg		Not Reported
	Nivaquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560475	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown	5 Milligram, Q12h		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021576		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Azathioprine			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	40 Milligram, Q2wk		Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Methotrexate	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560673	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021952		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	2.5 Milligram, Qd		Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561009	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020118255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate Sodium			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561066	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Atorvastatin Calcium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Alprazolam			C		1 Mg, Unk		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported
	Naprosyn [Naproxen]			C		500 Mg, 2x/Day		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561096	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA202009727			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)			Shire
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

	Tofacitinib Citrate		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561109	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Etanercept			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561711	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561810	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1206362		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydromorph Contin			C				Not Reported
	Prednisone			C				Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561811	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1206466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561822	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206400		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Alprazolam	C	Unknown		Not Reported
Amlodipine	C	Unknown	5 Milligram Daily;	Not Reported
Asa	C	Unknown		Not Reported
Bisoprolol Fumarate	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Paroxetine	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Risedronate Sodium	C	Unknown		Not Reported
Simvastatin	C	Unknown		Not Reported
Telmisartan	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561842	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206317		71 YR	Female	CAN

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

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561863	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206324		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561870	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206272		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Apo-Naproxen			C		1000 Milligram Daily;		Not Reported
	Apo-Prednisone			C				Not Reported
	Desoximetasone			C				Not Reported
	Ergocalciferol			C	Oral			Not Reported
	Folic Acid			C		1 Milligram Daily;		Not Reported
	Leucovorin Calcium			C				Not Reported
	Pantoprazole Magnesium			C		40 Milligram Daily;		Not Reported
	Pantoprazole Magnesium			C		1 Dosage Forms Daily;		Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral			Not Reported

	Wellbutrin	C	300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561877	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206389			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562040	NON-EXPEDITED			US-PFIZER INC-2020117515		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Ciprofloxacin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562446	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020116277		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Dobupal			S		Unk Unk, 1x/Day (1/24)		Pfizer
	Hydrochlorothiazide/Losartan Potassium			S		50 Mg/12.5 Mg		Not Reported

	Eutirox	S	Unk Unk, 1x/Day (1/24)	Not Reported
	Dolquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567649			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300-400 ; Ongoing		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Ongoing		Not Reported
	Simponi			S	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206591		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

	Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021523		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity;	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported

Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Somnolence; Visual Impairment	Humira	S	Subcutaneous	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
	Synthyroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13594604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941652		42 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13901217	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170125543		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hepatotoxicity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pain; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Gold	S	Unknown	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Actonel	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate Sodium	S	Other	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Adalimumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15385213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184735		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15625325	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557482-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15629661	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557290-00		59 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16122724	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	20 Nanogram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk, Qwk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	Unk, Q4wk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Acetaminophen & Cod. Phosp.			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16216662	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020655		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate			S	Unknown	16.35 Milligram, 1 Every 2 Weeks		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, 1 Every 1 Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actonel			S	Unknown	35 Milligram, 1 Every 1 Week		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Cyclical		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, One Every One Hour		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every Two Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, One Every One Hour		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times		Not Reported

				A Day	
	Hydroxychloroquine	S	Unknown	Unk, 1 Every 1 Week	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported
	Risedronate	C	Unknown	35 Milligram, Every Week	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16227903	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA020634			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Celebrex	S		Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	1 Dose	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Methadone	S		Unk	Not Reported
	Rampril	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
	Estrogel	C	Unknown	1.0 Df Qd	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, 2x/Day	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported

Vitamin D	C		10000 Unit, Weekly		Not Reported
Jamp K20	C		1500 Mg, 1x/Day		Not Reported
Zingiber Officinale	C	Oral	500 Mg, As Needed		Not Reported
Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day		Not Reported
Ergocalciferol	C	Unknown	Unk, Weekly		Not Reported
Ergocalciferol	C	Unknown	Unk, Qd		Not Reported
Morphine	C	Unknown	Unk Unk, As Necessary		Not Reported
Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)		Not Reported
Gravol Ginger	C	Oral	500 Milligram, As Needed		Not Reported
Baclofen	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16446297	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2822466-00		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16682901	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-22253		57 YR	Female	CAN

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

Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Off Label Use; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Adalimumab	S	Unknown	Unknown	Not Reported
	Cosentyx	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Otezla	S	Oral	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Acetaminophen And Codeine	C	Unknown		Not Reported
	Acetaminophen And Codeine	C	Unknown	Unknown	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Baclofen	C	Unknown	Unknown	Not Reported
	Betahistine Hydrochloride	C	Unknown	Unknown	Not Reported
	Caffeine	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Clonidine	C	Unknown	Unknown	Not Reported
	Clonidine Hydrochloride	C	Unknown	Unknown	Not Reported

	Esomeprazole Magnesium Trihydrate	C	Unknown	Unknown	Not Reported
	Fluticasone Propionate	C	Unknown	Unknown	Not Reported
	Folinic Acid	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Unknown	Not Reported
	Losartan	C	Unknown	Unknown	Not Reported
	Metoprolol Tartrate	C	Unknown	Unknown	Not Reported
	Mometasone Furoate	C	Unknown	Unknown	Not Reported
	Naproxen	C	Unknown	Unknown	Not Reported
	Naproxen	C	Unknown	Unknown	Not Reported
	Tylenol With Codeine	C	Unknown	Unknown	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Codeine	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16820459	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3442			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Product Use Issue; Rheumatoid Arthritis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17324085	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005924		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported

Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17439290	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011929		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Skin Eruption	Coumadine			S	Oral	Unk		Bristol Myers Squibb
	Innohep			S	Oral	Unk		Not Reported
	Omnipaque			S	Intravenous (not otherwise specified)	55 Milliliter		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17530620	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021584			Female	CAN

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

Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia	S	Intravenous (not otherwise specified)	Bristol Myers Squibb
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17549765	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-013114		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk,6 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563119	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022177		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	2 Dosage Form, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1 Dosage Form, Qd		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Microgram, Qd		Not Reported
	Zingiber Officinale			C	Oral	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566876		72 YR	Female	CAN

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

Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Celebrex	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous	Solution		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Prednisone	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C				Not Reported
	Simponi	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566890			Male	CAN

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

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Oral			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Methotrexate	S	Oral	Solution		Not Reported
Orencia	S	Unknown			Not Reported
Vioxx	S	Unknown			Not Reported
Naproxen	S	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563528	EXPEDITED (15-DAY)		HO, LT, OT	PT-ACCORD-176291		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal; Oedema Peripheral; Pericardial Drainage; Pericardial Effusion; Pericardiotomy; Pleural Effusion; Prohormone Brain Natriuretic Peptide Increased; Rales; Serositis	Mycophenolic Acid			S	Unknown	2.5 G, Qd		Accord
	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Not Reported
	Remodulin Sq			S	Subcutaneous	0.046 Mg, Q1hour		Not Reported
	Riociguat			C	Unknown	6 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563950	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564021	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001710			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Tenderness; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Herpes Simplex Hepatitis; Lethargy; Lymphopenia; Musculoskeletal Chest Pain; Nausea; Somnolence; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564032	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP008890			Female	CAN

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

Diarrhoea; Drug Intolerance; Maculopathy; Pneumonia; Product Use Issue; Visual Impairment	Leflunomide	S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine	S	Oral	400 Mg, Qd		Apotex
	Methotrexate	C	Subcutaneous	20 Mg, Unk		Not Reported
	Sulfasalazine	C	Unknown	500 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564060	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573629-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564141	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566946			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564456	EXPEDITED (15-DAY)		OT	CA-SA-2020SA067248			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Leflunomide			S		20 Mg, Qd		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566118	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-095261		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral	Alendronic Acid			S	Unknown	70 Milligram, 4 Every 1 Week		Aurobindo
	Apo-Alendronate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	12 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	12.5 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	17.5 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	15 Milligram, Every Week		Not Reported

Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Apo-Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	17.5 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	10 Milligram, Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram,Four In One Week	Not Reported
	Apremilast	S	Unknown	60 Milligram, Two Times A Day	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram,Two Every One Week	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Unknown	600 Milligram, Once A Day	Not Reported
	Ibuprofen	S	Unknown	Unk, Once A Day	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Motrin	S	Oral	600 Mg, Qd	Not Reported
	Motrin	S	Oral	Unk Unk, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S			Not Reported
Otezla	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram,One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Milligram,One Every Four Week	Not Reported
Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Humira	C	Unknown	40 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,Four Every	Not Reported

				1 Week	
	Methotrexate	S	Unknown	12 Milligram,Four Every 1 Week	Not Reported
	Methotrexate	S	Unknown	70 Milligram, Every Week	Not Reported
	Mogadon	C	Oral	5 Milligram	Not Reported
	Nitrazepam	C	Unknown	5 Milligram	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	20 Milligram	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	C	Unknown	680 Milligram	Not Reported
	Tocilizumab	C	Unknown	360 Milligram	Not Reported
	Uloric	C	Unknown	80 Milligram, Two Times A Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566974	EXPEDITED (15-DAY)		OT	NVSC2020CA079201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Disorder; Off Label Use; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Arava	C	Unknown	Unk		Not Reported
Desvenlafaxine Succinate	C	Unknown	Unk		Not Reported
Leflunomide	C	Oral	20 Mg, Qd		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Quetiapine Fumarate	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567557	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022569		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D 3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567671	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA078923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off	Cosentyx			S	Unknown	Unk		Novartis

Label Use	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk (Solution)	Not Reported
	Stelara	S	Subcutaneous	Unk (Solution)	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567912	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022607		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

Failure; Viral Upper
Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567934	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022780		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568087	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022579		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Not Reported
	Plaquenil S			S	Unknown	200.0 Milligram, Qwk		Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568106	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022615		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 1 Every 1 Days		Not Reported
	Morphine			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568289	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qw		Not Reported

Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	C				Not Reported
Wellbutrin	C				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15624381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556781-00		62 YR	Female	CAN

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

	Prednisolone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15625734	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557153-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo Prednison			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	16718423	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892907-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17563703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3328160-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Pneumothorax	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17567968	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2020025732			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Clopidogrel			S	Unknown	Unk		Macleods
	Atorvastatin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17572435	DIRECT					39 YR	Female	USA

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

Blindness Unilateral	Hydroxychloroquine	Y	S	6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	13186699	EXPEDITED (15-DAY)		OT	CA-ROCHE-1888735		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15328456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175439			Female	CAN

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

	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15683363	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574500-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17530404	EXPEDITED (15-DAY)		OT	NVSC2020CA070217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Otezla	S	Unknown	Unk		Not Reported
Otezla	S	Oral	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Subcutaneous	Unk		Not Reported
Stelara	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17542710	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA071289		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported

	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Naprosyn		C	Unknown			Not Reported
	Erythromycine		C	Unknown	Unk		Not Reported
	Morphine		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17545270	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Somnolence; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Tylenol			S	Unknown			Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17569409	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022556		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram 1 Every 1 Months		Not Reported
	Alendronate			S	Unknown	70 Milligram 1 Every 1 Weeks		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	12.0 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	10.0 Milligram 1 Every 1 Weeks		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown	1000 Milligram 2 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram 1 Every 1 Weeks		Not Reported

Methotrexate	S	Oral	10 Milligram 1 Every 1 Weeks		Not Reported
Ciclosporin	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13251292	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006546		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Hydroxychloroquine			S	Oral	400 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	0.8 Ml, Q.Wk.		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14757583	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009592			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Penicillin			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Aspirin /00002701/	S	Unknown	Unk		Not Reported
Penicillin G /00000901/	S	Unknown	Unk		Not Reported
Penicillin G Potassium	S	Unknown	Unk		Not Reported
Penicillin G Procaine	S	Unknown	Unk		Not Reported
Pregabalin	C	Unknown	Unk		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15619609	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555410-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	11 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Xeljanz	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15623842	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557025-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Toe Amputation; Victim Of Crime	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Ophthalmic			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16357705	EXPEDITED (15-DAY)			CA-ORION CORPORATION ORION PHARMA-TREX2019-1532			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Estradot	S	Transdermal	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16473931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1994		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Inflammation; Joint Stiffness; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Subcutaneous	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Lymphoma; Thyroid Disorder	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023149			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Endocervical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569480	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001670			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1000 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Gliclazide			C		Unk		Not Reported

Vimovo	C	Unk	Not Reported
Rabeprazole	C	Unk	Not Reported
Mr	C	Unk	Not Reported
Metformin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569650	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022575		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Alendronate			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported

Rituximab	S	Intravenous drip	1000 Milligram, Bid		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Ciclosporin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569669	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023123			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569671	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022648		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569754	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565726		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569843	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022714		83 YR	Female	CAN

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

Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, Qmo	Not Reported
	Arava	S	Intravenous (not otherwise specified)	20 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Gabapentin	S	Unknown	100 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	2.5 Gram, Qd	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported

	Prednisone	C	Unknown	5 Gbq 1 Every 1 Day	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Qd	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
	Tylenol	C	Unknown	1000 Milligram, Qd	Not Reported
	Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569878	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1451			Male	CAN

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

Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Atorvastatin Calcium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Alprazolam	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570139	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201611-005804			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Unk		Concordia
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	20 Mg (Tablet)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not	2 G,Qcy; Iv Nos		Not Reported

			otherwise specified)		
	Rituxan	S	Unknown	2 Unk, Qcy; Unknown	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m; Iv Nos	Not Reported
	Etanercept	S		50 Mg, Weekly	Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570142	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000092			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Levothyroxin			C		Unk		Not Reported
	Raloxifene			C		Unk		Not Reported
	Lidoderm			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570259	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb

Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unk Unk, Qd	Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral	Unk Unk, Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Intra-articular		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rash	Leflunomide			S		10 Mg		Sanofi
	Plaquenil			S	Oral	200 Mg, Q12h		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570308	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068804			Male	CAN

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

Drug Ineffective; Interstitial Lung Disease	Leflunomide		S	Unknown	Unk	Sanofi
	Plaquenil		S	Unknown	400 Mg	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570311	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068793			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatotoxicity; Rash; Treatment Failure	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S		1 Df		Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S		1 Df		Not Reported
	Orencia			S	Subcutaneous	125 Df, Qw		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570367	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023442		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Other	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570370	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-01473		52 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Lupin
	Prednisone			S	Unknown	60 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	20 Milligram, Qd In 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570449	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2500975-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Platelet Count Decreased; Rhinorrhoea; Skin Mass	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Synthetic Morphine			C	Unknown	Unknown Dose 1 Or 2		Not Reported
	Tylenol			C		Unknown Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571132		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz Xr	C	Oral	Not Reported
	Xeljanz Xr	C	Unknown	Not Reported
	Xeljanz Xr	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570607	EXPEDITED (15-DAY)		OT	NVSC2020CA077910		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	6.78 Mg/Kg (Cumulative Dose 1.24 Kg)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570792	EXPEDITED (15-DAY)		OT	NVSC2020CA079412		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported

Plaquenil	S	Unknown	Unk		Not Reported
Remicaide	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571152	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118213			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		20 Mg		Pfizer

	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571456	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA079635		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Oral	75 Mg, Bid		Novartis
	Apo Diclo			S	Oral	75 Mg, Bid		Not Reported
	Apo Lisinopril			S	Oral			Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac Potassium			S	Oral	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported
	Lisinopril			S	Unknown			Not Reported
	Lisinopril Dihydrate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Pantoprazol			S	Unknown			Not Reported
	Pantoprazol			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Synthroid			S	Oral			Not Reported
	Tecta			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Mg, Qd		Not Reported
	Gold			C	Unknown			Not Reported
	Depo-Medrol			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572087	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572243	EXPEDITED (15-DAY)		OT	US-SA-2020SA071865			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium; Drug Interaction; Retinopathy; Visual Field Defect	Hydroxychloroquine			S				Sanofi
	Docetaxel			S				Sanofi
	Anastrozole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572378	EXPEDITED (15-DAY)		OT	NVSC2020CA079465			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573060	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1029307			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Serositis	Mycophenolate Mofetil			S	Unknown	2.5 Gram		Not Reported
	Bosentan			S	Unknown	250 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Mylan
	Prednisolone			S	Unknown	5 Milligram		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg/H, Continuing		Mylan
	Riociguat			C	Unknown	6 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573076	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA079709		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573103	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1031278		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	For 6 Weeks		Not Reported
	Prednisone			S	Oral	1 Milligram/Kilogram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573142	EXPEDITED (15-DAY)		OT	NVSC2020CA079502		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573170	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023021		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor	Orencia			S	Unknown			Bristol Myers Squibb

Positive; Therapeutic Product Effect Decreased	Actemra	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Q2wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk, Q6wk	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573206	EXPEDITED (15-DAY)		OT	NVSC2020CA079493		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Unknown	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Depo-Medrol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573227	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023154			Female	CAN

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

Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Subcutaneous	1 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Topicort Lp	S	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023109		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulphate	S	Unknown	Unk		Not Reported
Infliximab	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
Prednisone	C	Unknown	30 Milligram, Qd		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573405	NON-EXPEDITED			NVSC2020US082232			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Hydroxychloroquine			S	Oral	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17581632	DIRECT					66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Plaquenil			S	Oral			Not Reported
	Tirosint			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	14498265	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007254			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Hypoglycaemia; Lymphoma; Off Label Use; Thyroid Disorder	Arava		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous drip		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15632850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105426		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15707284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584423-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15712957	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588343-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Certolizumab Pegol		S	Unknown		Not Reported
	Azathioprine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16836959	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27185		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

Ciclosporin	S	Oral	Unknown	Not Reported
Ciclosporin	S	Oral	Unknown	Not Reported
Ciclosporin	S	Unknown	Unknown	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
Cimzia	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown		Not Reported

Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown		Not Reported
Piroxicam	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16977712	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001380			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Neutropenia; Pain In Extremity; Rash; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	Unk, Weekly		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported
	Flurbiprofen			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

	Prevacid	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574330	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201711-006281			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	300 Mg		Concordia
	Arava			S	Oral	10 Mg		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly; Solution		Not Reported
	Methotrexate			S	Unknown	12.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Weekly		Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Enbrel	S	Unknown	50 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Every Six Weeks	Not Reported
	Orencia	S	Subcutaneous	25 Mg	Not Reported
	Bifidobacterium Bifidum	C			Not Reported
	Prednisone	C			Not Reported
	Sulfasalazine	C			Not Reported
	Celebrex	C			Not Reported
	Loperamide	C			Not Reported
	Pantoprazole	C			Not Reported
	Xeljanz	C			Not Reported
	Simponi	C			Not Reported
	Wellbutrin	C			Not Reported
	Plaquenil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574349	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005363			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Weekly		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported

Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk, Solution Subcutaneous	Not Reported
	Methotrexate	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tylenol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574713	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023101		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574715	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate			S	Oral	35 Milligram, Every Week		Aurobindo
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Milligram, Two Times A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	1 Gram, Two Times A Day		Not Reported
	Azathioprine			C	Oral	50 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	150 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	100 Milligram, Two Times A Day		Not Reported
	Humira			C	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported
	Ketoprofen			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Every Week		Not Reported
	Prolia			C	Subcutaneous	60 Milligram (1 Every 6 Months)		Not Reported

	Rituximab	C	Intravenous (not otherwise specified)	1 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574931	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	300-400 Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575142	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000867			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hyperhidrosis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Ipca
	Prednisolone			C	Unknown	Unk, Take As Directed		Not Reported
	Dermol			C	Unknown	Unk, Use As Directed		Not Reported
	Dermovate			C	Unknown	Unk, Apply 1-2 Times/Day Thinly To All Affected Areas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575254	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023112		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported

Enbrel	S	Subcutaneous	50 Milligram		Not Reported
Humira	S	Subcutaneous	20 Milligram, Qd		Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 4 Every 1 Week		Not Reported
Prednisone	S	Oral	5 Milligram, Qd		Not Reported
Sulfasalazine	S	Unknown	1000 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575456	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Intentional Product Use Issue; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Orencia			S	Intracavernous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, 2 Every 1 Day		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported

Diphenhydramine	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575525	NON-EXPEDITED			US-PFIZER INC-2020123929		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Therapeutic Product Effect Incomplete	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575752	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023400		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Methotrexate	S	Subcutaneous	15 Milligram, Qwk		Not Reported
Sulfasalazine	S	Oral	1 Gram, Qd		Not Reported
Xeljanz	C	Oral	5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575760	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020120639			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575864	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567757		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17576658	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Unknown			Not Reported
	Prednisone			C	Unknown	50 Milligram, 1 Every 1 Day		Not Reported
	Prevacid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	50 Milligram, 2 Every Q Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577584	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023530			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver	Orencia			S	Unknown			Bristol Myers Squibb

Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown	162 Milligram		Not Reported
	Cimzia	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Unknown			Not Reported
	Azathioprine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577628	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023475		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023552		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023607		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown	100 Milligram		Not Reported

Ativan	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Darifenacin	C	Unknown		Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Dilaudid	C	Unknown		Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Rituximab	C	Intravenous (not otherwise specified)	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Vagifem	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Actemra	S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
Enbrel	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578006	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023868			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578076	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	15 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578415	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020123955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578942	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024664		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578947	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024594		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578991	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024991			Male	CAN

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

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14145032	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-095890			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Drug Ineffective; Hospitalisation; Meningitis; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	15949326	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16073575	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05670		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16125465	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unk Unk, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	40 Mg (Titer), Q2wk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740243	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA196426		64 YR	Female	CAN

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

Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Aclasta	S	Intravenous (not otherwise specified)	Unk	Novartis
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	1 Df, Qd	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Tramacet	S	Unknown		Not Reported
	Actonel	C	Unknown	35 Mg, Qw	Not Reported
	Calcium	C	Unknown		Not Reported
	Lorazepam	C	Unknown	1 Mg, Qd	Not Reported
	Lyrica	C	Oral	150 Mg, Bid	Not Reported
	Metformin	C	Unknown	5 Mg, Qd	Not Reported
	Metformin	C	Unknown	500 Mg, Bid	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported

	Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C			Not Reported
	Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Mg, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	35 Mg, Every Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740961	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-2386588			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthralgia; Arthropathy; Atrial Fibrillation; Bronchitis; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Roactemra			S	Subcutaneous			Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Ambrisentan			S	Unknown	30 Mg, Qd		Not Reported
	Ambrisentan			S	Unknown	30 Milligram, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid (1 - 1 - 1)		Not Reported
	Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Spasmolyt			S	Unknown	30 Mg (0 -0 -1)		Not Reported
	Spasmolyt			S	Unknown	15 (Unit Not Specified), Qd ((1 - 0 - 0)		Not Reported
	Omeprazole			S	Oral	1 Df, Bid (1 - 0 - 1)		Not Reported
	Ramipril			S	Oral	1 Df, Bid (1 - 0 - 1)		Not Reported
	Eliquis			S	Unknown	2.5 Mg Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17390605	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-006953		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram(2 Every One Week)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578578	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Unknown	500 Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not	8 Milligram/Kilogram		Not Reported

			otherwise specified)		
	Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
	Leflunomide	S	Oral	20 Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578721	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001831			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Diarrhoea; Nausea; Nightmare; Renal Pain; Sleep Terror; Therapeutic Response Decreased; Treatment Failure; Weight Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Weekly		Not Reported
	Azathioprine			C				Not Reported
	Humira			C		Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Prevnar 13			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578725	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001913			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unknown, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unknown		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rocuronium Bromide			S	Unknown	Unknown		Not Reported
	Rocuronium Bromide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unknown		Not Reported
	Benzylpenicillin Sodium			S	Unknown	Unknown		Not Reported
	Phenoxymethylpenicillin Potassium			S	Unknown	Unk		Not Reported

	Rituximab		S	Unknown	Unk	Not Reported
	Prednisone		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023426		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568831		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tacrolimus	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578910	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579095	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Leflunom|De			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579314	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES			Unknown	USA

LIMITED-IPC-2020-US-000918

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Cardiotoxicity; Renal Impairment	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Furosemide			S	Intravenous (not otherwise specified)	Unk		Ipca
	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579324	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1483			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579472	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567801		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579865	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1208924		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Levofloxacine			S	Oral	1000 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	2 Dosage Forms		Not Reported

	Ideos	S	Oral	2 Dosage Forms	Not Reported
	Acarizax	S	Oral		Not Reported
	Lutenyl	C			Not Reported
	Cortancyl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025463		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580309	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023667		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported

	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581498	NON-EXPEDITED			US-PFIZER INC-2020122192		72 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581877	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Weight Gain; Alopecia; Chest Pain; Dizziness; Dyspnoea; Fatigue; Joint Swelling; Nausea; Photosensitivity Reaction; Syncope; Tremor	Hydroxychloroquine 200 Mg			S	Oral	Quantity:2 Tablet(S);	5 YR	Not Reported
	Prem-Pro 0.3mg/1.5mg			C				Not Reported
	Ventolin Inhaler			C				Not Reported
	Vit B (Complex)			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Cod Liver Oil			C				Not Reported

	Grape Seed Extract	C	Not Reported
	St Johns Wort	C	Not Reported
	Stainging Nettle	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581909	EXPEDITED (15-DAY)		DE, HO, LT, OT	NVSC2020CA083709			Male	CAN

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

				otherwise specified)		
	Remicade		S			Not Reported
	Sulfasalazine		S	Unknown	500 Mg	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581930	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030615		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction	Methotrexate			S	Subcutaneous	10 Milligram, Qw		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid (12 Hours)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581934	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate Sodium			S	Intra-arterial	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Oxyquinoline Sulfate	S	Unknown	Unk		Not Reported
Oxyquinoline Sulfate	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581969	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030618		30 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Mycophenolate Mofetil			S	Oral	500 Milligram, Bid		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid		Mylan
	Rituximab			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583060	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025465		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Anakinra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583075	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583096	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025534			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea;	Orencia			S	Intravenous (not			Bristol Myers Squibb

Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased			otherwise specified)			
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	12914312	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091576		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported

Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Adalimumab	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk, Qd	Not Reported
	Gold	S	Unknown	Unk, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Parenteral	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram, Qwk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd	Not Reported

Ciclosporin	C	Unknown	Unk		Not Reported
Minocycline	C	Unknown	Unk		Not Reported
Penicillamine	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	6 Milligram, Bid		Not Reported
Actemra	C	Unknown	Unk		Not Reported
Cyclosporine	C	Unknown	Unk		Not Reported
Prednisolone	C	Unknown	6 Milligram, Qd		Not Reported
D-Penicillamine	C	Unknown	Unk		Not Reported
Phenylbutazone	C	Unknown			Not Reported
Methotrexate	C	Parenteral	25 Milligram, Q4wk		Not Reported
Humira	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057420	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1869749		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057569	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015705		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Advil /00109201/			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ketorolac			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13180365	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA012856		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction;	Methotrexate			S	Unknown	Unk		Not Reported
	Neoral			S	Unknown	Unk Unk, Unknown		Novartis

Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Celebrex		S	Unknown	Unk Unk, Unknown	Not Reported
	Cimzia		S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Enbrel		S	Unknown	Unk Unk, Unknown	Not Reported
	Humira		S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Imuran		S	Unknown	Unk Unk, Unknown	Not Reported
	Plaquenil		S	Unknown	Unk Unk, Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk, Unknown	Not Reported
	Azathioprine		S	Unknown	Unk	Not Reported
	Celecoxib		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13968018	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017267		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased;	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not	200 Mg, Unk		Not Reported

Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed			otherwise specified)		
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Unk	Not Reported
	Cortisone	C	Unknown		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Naprosyn /00256201/	C	Unknown		Not Reported
	Rabeprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	14692979	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2018CA055436		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Sulfasalazin			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazin			S				Not Reported

Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Xeljanz	C	Oral	2 Df, Qd	Not Reported
	Xeljanz	C	Unknown	5 Mg	Not Reported
	Rituximab	C	Unknown		Not Reported

	Kineret	C	Unknown	Unk		Not Reported
	Lyrica	C	Unknown			Not Reported
	Prednisone	C	Unknown	1 Df, Qd		Not Reported
	Urelumab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15411090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186044		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15635401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25.0 Mg, Qwk		Not Reported

Myochrysine	S	Intramuscular	25 Mg, Qwk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Gold Sodium Thiomalate	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15867265	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190123564		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Simponi Iv			S	Intravenous (not otherwise specified)			Not Reported
	Simponi Iv			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15946323	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010990		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Codein			C	Unknown			Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16480411	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-16027		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported

Cell Sedimentation Rate Abnormal; Treatment Failure	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16792405	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2019JPN160709		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Segmental Glomerulosclerosis	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Predonine			C		Unk		Not Reported
	Mycophenolate Mofetil Capsule			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16982578	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20191009548		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Otezla			S	Unknown	60 Milligram		Celgene

Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla	S	Unknown		Celgene
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Ibuprofen	S	Oral		Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Infliximab	S	Oral		Not Reported
	Infliximab	S			Not Reported
	Methotrexate	S	Unknown	1.7143 Milligram	Not Reported
	Methotrexate	S	Unknown	1.7857 Milligram	Not Reported
	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	2.5 Milligram	Not Reported
	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	7.1429 Milligram	Not Reported
	Methotrexate	S	Unknown	5.7143 Milligram	Not Reported
	Methotrexate	S	Unknown	6.8571 Milligram	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Mogadon	C	Oral		Not Reported

	Nitrazepam	C	Oral	5 Milligram		Not Reported
	Oxycodone	C	Unknown			Not Reported
	Prednisone	C	Unknown	20 Milligram		Not Reported
	Uloric	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16988122	EXPEDITED (15-DAY)		OT	CA-SA-2019SA298961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Cefixime			S	Unknown	Unk		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Salt Not Specified			S				Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown			Sanofi
	Zopiclone			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg Q0, 2, 6, 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17455140	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000974			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During	Hydroxychloroquine			S		Unk		Concordia

Pregnancy; Toxicity To Various Agents	Hydroxychloroquine	S		400 Mg, Qd	Concordia
	Hydroxychloroquine	S		Unk	Concordia
	Azathioprine	S		50 Mg, Qd	Not Reported
	Azathioprine	S		Retreatment With Low-Dose 50 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S		Moderate Doses Of Prednisone	Not Reported
	Prednisone	S		2.5 Mg, Qd	Not Reported
	Belimumab	S		Unk	Not Reported
	Belimumab	S		10 Mg/Kg, Monthly	Not Reported
	Belimumab	S		Unk, Resumed 2 Weeks After Delivery	Not Reported
	Mycophenolate	C		Unk	Not Reported
	Mycophenolate	C		Switching Back	Not Reported
	Mycophenolate	C		Continued During The Initial 6 Months Of Belimumab Infusions And Then Tapered Off	Not Reported
	Warfarin	C		Unk	Not Reported
	Warfarin	C		Resumed Warfarin	Not Reported
	Low-Molecular-Weight Heparin	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024031		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb

Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus				otherwise specified)		
	Actemra		S	Unknown	Unk	Not Reported
	Apo-Prednisone		S	Unknown	5 Milligram	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Desoximetasone		S	Oral	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Folic Acid		S	Unknown	500 Milligram	Not Reported
	Fosamax		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Q12h	Not Reported
	Methotrexate		S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025557		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583283	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000888			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Warfarin Sodium			S	Unknown	Unk		Ipca
	Clopidogrel			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			C	Unknown	Unk		Not Reported
	Isoniazid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568766			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported

	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569483		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023661		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	40 Milligram		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfathalidine		S	Unknown	Unk	Not Reported
	Diclofenac		C	Unknown	50 Milligram	Not Reported
	Salazopyrin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583562	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1479		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583564	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583582	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION			Male	CAN

PHARMA-TREX2020-1504

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583834	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001844			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Rash	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Salazopyrin			C		Unk		Not Reported
	Solganal			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Flurbiprofen			C		Unk		Not Reported
	Cortisone			C	Intra-articular	Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Gold			C		Unk		Not Reported
	Prevacid			C		Unk		Not Reported
	Penicillamine			C		Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583878	NON-EXPEDITED		DE	NVSC2020US084343		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Unknown	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Unknown	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 400 To 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567774		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583952	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584003	EXPEDITED (15-DAY)		HO	CA-ROCHE-2571253			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584031	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241562		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Resistance; Gastrointestinal Disorder; Pseudomonal Skin Infection; Therapeutic Product Effect Incomplete; Treatment Failure	Triamcinolone			S		Unk		Ranbaxy
	Tacrolimus			S	Topical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Clobetasol			S	Topical	Unk		Taro
	Pentoxifylline			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584216	EXPEDITED (15-DAY)		OT	NVSC2020CA082940		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Adalimumab			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported

Xeljanz	S	Oral	Unk	Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Sulfasalazine	S	Oral	1 Df, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	75 Mg, Qmo	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	2000 Mg, Bid	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	40 Mg, Q2w	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown	Not Reported
Arava	C	Oral	1 Df, Qd	Not Reported
Cimzia	C	Subcutaneous	1 Df, Q2w	Not Reported
Risedronate	C	Oral	1 Df, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584625	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127462		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

	Leflunomide		S	Oral	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584988	EXPEDITED (15-DAY)		OT	GB-TORRENT-00023236		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Apixaban			S	Unknown	Unknown		Unknown
	Warfarin			S	Unknown	Unknown		Unknown
	Rivaroxaban			S	Unknown	Unknown		Unknown
	Clopidogrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Unknown
	Atorvastatin			S	Unknown	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Azathioprine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous	Solution		Not Reported
	Minocycline	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown			Not Reported
	Amoxil [Amoxicillin]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Cbd Oil			C				Not Reported
	Dronabinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585240	EXPEDITED (15-DAY)		OT	NVSC2020CA083916		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported

Intolerance; Fatigue; Off Label Use; Treatment Failure	Leflunomide	S	Unknown	Unk	Not Reported
	Neoral	S	Oral	Unk	Novartis
	Rituximab	S	Endocervical	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Novartis
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Unknown	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown	Not Reported
	Simponi	S	Subcutaneous	Unk (Solution)	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, Qd 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585303	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075074		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib Citrate			S				Not Reported
	Actemra			S				Not Reported
	Diovan			C				Not Reported
	Docosahexanoic Acid;Eicosapentaenoic Acid			C				Not Reported

	Sertraline	C	Not Reported
	Valtrex	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585304	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075084		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Arava			S	Unknown			Sanofi
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585306	EXPEDITED (15-DAY)		OT	CA-SA-2020SA074997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Gastrointestinal Disorder; Rash	Plaquenil			S		Unk G		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			C		2 G		Not Reported
	Venlafaxine Hydrochloride			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585763	EXPEDITED (15-DAY)		OT	NVSC2020CA083797		51 YR	Female	CAN

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

Drug Ineffective; Off Label Use; Treatment Failure	Neoral		S	Subcutaneous	Unk	Novartis
	Neoral		S	Subcutaneous	Unk	Novartis
	Cyclosporine		S	Unknown	Unk	Novartis
	Methotrexate		S	Oral	20 Mg	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Actemra		S	Intravenous drip	8 Mg/Kg, Unk	Not Reported
	Actemra		S	Intravenous drip	8 Mg/Kg, Unk	Not Reported
	Enbrel		S	Subcutaneous	500 Mg (Every 1 Weeks)	Not Reported
	Orencia		S	Subcutaneous	125 Mg	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Plaquenil		S	Subcutaneous	Unk	Not Reported
	Remicade		S	Intravenous drip	3 Mg/Kg,Unk	Not Reported
	Xeljanz		C	Oral	5 Mg (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585786	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031634		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585836	EXPEDITED (15-DAY)		OT	NVSC2020CA083902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug	Methotrexate Sodium			S	Subcutaneous	20 Mg, (16 Years)		Not Reported
	Neoral			S	Oral	20 Mg (16 Years)		Novartis

Ineffective; Rheumatoid Arthritis	Enbrel		S	Subcutaneous	50 Mg (3 Months)	Not Reported
	Plaquenil		S	Oral	20 Mg (16 Years)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3.0 Mg/Kg (12 Years)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025893		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586685	NON-EXPEDITED		DE	NVSC2020US084340		59 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Oral	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Oral	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Oral	400- 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587086	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024299		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Risedronate	S	Oral	35 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587200	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2018488256		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Product Use In Unapproved Indication; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587547	EXPEDITED (15-DAY)		OT	NVSC2020CA084494		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Unknown	Unk		Novartis
	Cyclosporine			S	Unknown			Novartis
	Leflunomide			S	Unknown	20.0 Mg, Qd		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous	20.0 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Cimzia			C	Subcutaneous	200.0 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587578	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031637		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Dapsone			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587783	NON-EXPEDITED			NVSC2020US083346			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xolair			S	Unknown	Unk, Q4w		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Dupilumab			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Lycor			S	Unknown			Not Reported
	Singulair			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588436	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025383		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588455	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588457	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026044		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Mg 3 Every 2 Days		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported
	Ebastine			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Methylprednisolone Acetate			C	Intra-articular	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17591609	DIRECT	Y	LT			65 YR	Male	USA

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

Electrocardiogram Qt Prolonged; Haemodialysis; Intensive Care	Plaquenil			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12893895	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150810477		70 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13059056	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015753		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Leflunomide			S		20 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	2 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	250 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13519394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038533		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Sulfasalasin			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15978351	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013839		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Oral	200 Milligram, Q12h		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Oral	500 Milligram, Q12h		Not Reported
	Arava	C	Unknown	20 Milligram, Qd		Not Reported
	Xeljanz	S	Oral	5 Milligram, Q12h		Not Reported
	Rituximab	S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16108792	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA062642			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S				Not Reported

	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16889106	EXPEDITED (15-DAY)		OT	CA-SA-2019SA271272			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17335679	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-HORIZON-PRE-0036-2020			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Prednisone			S	Transplacental	Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Vitamin D [Colecalciferol]			S	Transplacental	Unk		Not Reported
	Folic Acid			S	Transplacental	Unk		Not Reported
	Cefixime			S	Transplacental	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Ornidazole			S	Transplacental	Unk		Not Reported

Magnesium Lactate	S	Transplacental	Unk	Not Reported
Vitamin K Nos	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Vulmizolin	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S		Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Potassium Chloride	S	Transplacental	Unk	Not Reported
Fluconazole	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk	Not Reported
Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported
Hydrocortisone	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Nadroparine	S	Transplacental	Unk	Not Reported
Etamsylate	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
Albumin	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17530878	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001243			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hypersensitivity; Nausea; Rheumatoid Arthritis; Urticaria; Vertigo; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported

Tylenol	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17552501	EXPEDITED (15-DAY)		OT	GB-CELLTRION INC.-2020GB020489			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram		Not Reported
	Prednisolone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578248	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1031689		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal; Oedema Peripheral; Pericardial Effusion; Pericardiotomy; Pleural Effusion; Prohormone Brain Natriuretic Peptide Increased; Rales; Serositis	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Mylan
	Mycophenolate Mofetil			S	Unknown	2.5 G, Qd		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Riociguat			C	Unknown	6 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588707	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025879		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Mefenamic Acid	C	Unknown			Not Reported
Prednisone	C	Oral	6 Milligram, Qd		Not Reported
Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588868	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0830		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported

	Apo-Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588873	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588875	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588876	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17589340	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-20_00008751		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease;	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Device Dislocation; Pneumonia	Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590071	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241501		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590113	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075134			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Atorvastatin Calcium			S				Not Reported
	Leflunomide			S				Sanofi
	Pregabalin			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Trichlormethiazide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075141			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

Sedimentation Rate	Golimumab	S	Not Reported
Abnormal; Rheumatoid	Humira	S	Not Reported
Arthritis; Therapeutic	Infliximab	S	Not Reported
Product Effect Decreased	Otezla	S	Not Reported
	Acetaminophen	C	Not Reported
	Advair	C	Not Reported
	Allopurinol	C	Not Reported
	Atrovent Hfa	C	Not Reported
	Codeine	C	Not Reported
	Cyclobenzaprine Hydrochloride	C	Not Reported
	Dilaudid	C	Not Reported
	Hydromorphone Hydrochloride	C	Not Reported
	Ibuprofen	C	Not Reported
	Leucovorin Calcium	C	Not Reported
	Nexium [Esomeprazole Sodium]	C	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Not Reported
	Sulfasalazine	C	Not Reported
	Ventolin Hfa	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590669	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2020-AMRX-00900		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Cyclophosphamide			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Docetaxel			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Anastrozole			S	Unknown	21-Day Cycle, 4 Cycles)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	7.1 Mg/Kg Real Body Weight, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590700	EXPEDITED (15-DAY)		HO	US-GYP-000097		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Herpes Simplex;	Prednisone			S	Unknown	5 Mg Daily		Geneyork Pharma

Trichomoniasis	Hydroxychloroquine	S	Unknown	200 Mg Twice Daily		Not Reported
	Metronidazole	S	Oral			Not Reported
	Paracetamol	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591184	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026344		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591627	DIRECT		HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Folliculitis; Oral Disorder; Pharyngeal Disorder; Skin Swelling; Therapy Cessation; Urticaria; Urticaria	Hydroxychloroquine (Plaquenil)			S	Oral			Not Reported
	Pravastatin			C				Not Reported
	Fosomax			C				Not Reported
	Prempro			C				Not Reported
	Premarin			C				Not Reported
	Sipronlactone			C				Not Reported

	Minoxidil	C	Not Reported
	Doxycycline	C	Not Reported
	Omeprazole	C	Not Reported
	Singular	C	Not Reported
	Ventolin	C	Not Reported
	Azelastine	C	Not Reported
	B-Complex	C	Not Reported
	Triple Omega Fish Oil	C	Not Reported
	Calcium	C	Not Reported
	Vit. D-3	C	Not Reported
	Evening Primrose	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591702	EXPEDITED (15-DAY)		OT	NVSC2020CA083830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Methotrexate			S	Unknown	25 Mg, Unknown		Not Reported
	Tacrolimus			S	Oral	2 Mg, Q12h		Novartis
	Tacrolimus			S	Oral	3 Mg, Q12h		Novartis
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rapamune			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591728	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085589		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591840	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591841	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026360		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium			C	Unknown	500 Milligram, Qd		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown	0.6 Percent, Tid		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Gravol			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported

Valsartan	C	Unknown	320 Milligram, Qd		Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591942	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085582			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591972	NON-EXPEDITED			US-SA-2018SA048629			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Liver Function Test Increased	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S		Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17592969	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068673		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	40 Mg		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S		10 Mg		Not Reported
	Kevzara			S				Sanofi
	Sulfasalazine			S				Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported

	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	C		10 Mg	Not Reported
	Rabeprazole Sodium	C		20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17593152	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594000	EXPEDITED (15-DAY)		OT	NVSC2020CA083912		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous	Neoral			S	Unknown	125 Mg, Bid, (2 Every 1 Day)		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unknown		Not Reported
	Arava			S	Unknown	20 Mg, Qd, (Every 1 Day)		Not Reported
	Azathioprine Sodium			S	Unknown	150 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw, (1 Every 1 Week)		Not Reported

Cell Carcinoma Of Skin; Treatment Failure	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Imuran	S	Unknown	150 Mg, Tid, (3 Evey 1 Day)	Not Reported
	Methotrexate	S	Oral	1 Df, Qw, (1 Every 1 Week)	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid (2 Every 1 Day)	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid, (2 Every 1 Day)	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg, Qd (Every 1 Day)	Not Reported
	Citalopram Hydrobromide	C	Unknown	1 Df, Qw	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd (Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594417	EXPEDITED (15-DAY)		DE, HO	NVSC2020CA085101		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17431505	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1186390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Hydroxychloroquine			S	Unknown			Teva
	Trametinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595044	EXPEDITED (15-DAY)		OT	IT-ACCORD-177503		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S				Accord
	Dabigatran			S	Oral			Not Reported
	Daparox			S				Not Reported
	Lamictal			S				Not Reported
	Plaquenil			S				Not Reported
	Valium			S				Not Reported
	Sotalol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595150	NON-EXPEDITED			NVSC2020US086178			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17597821	DIRECT		DS			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Eye Disorder; Vascular Device User	Hydroxychloroquine	Y		S	Oral	Quantity:1 Tablet(S);		Unknown
	Orencia	Y		S	Intramuscular	Quantity:1 Injection(S);Other Frequency:Once A Week;		Er Squibb
	Heart Meds			C				Not Reported
	Diabetes Meds			C				Not Reported
	Inhalers			C				Not Reported
	Med For Migraines			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17598592	DIRECT		DS			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness; Manufacturing Materials Issue; Product Complaint; Product Substitution Issue; Therapy Non-Responder	Hydroxychloroquine 200mg Tab			S				Dr Reddys
	Omeprazole			C				Not Reported
	Hydroxychloroquinine			C				Not Reported
	Clarinex			C				Not Reported
	Turmeric			C				Not Reported
	Iron			C				Not Reported
	Mvi			C				Not Reported
	Vitamind3			C				Not Reported
	Aleve			C				Not Reported
	Tylenol			C				Not Reported
	Pseudoephedrine			C				Not Reported
	Guaifenesin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12351402	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK063971		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Glaxosmithkline
	Cortisone			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S		Unk		Not Reported
	Desoximetasone			S		Unk		Not Reported
	Diclofenac Potassium			S		Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	13502224	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14547629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-040466		28 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Sinusitis; Anaphylactic Shock; Anxiety; Bronchitis; Depression; Device Malfunction; Electric Shock; Faeces Soft; Fatigue; Gait Disturbance; Headache; Influenza Like Illness; Long Qt Syndrome; Mouth Ulceration; Nausea; Off Label Use; Pain; Productive Cough; Pyrexia; Seasonal Allergy; Secretion Discharge; Sinusitis; Tongue Ulceration; Upper Respiratory Tract Infection Bacterial	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported
	Leucovorin [Folinic Acid]			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14918934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043916		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate	Orencia			S	Subcutaneous	750 Mg, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Gram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Tid		Not Reported

Abnormal; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	2000 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Mg, Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	15551969	EXPEDITED (15-DAY)		OT	PHHY2018CA135990		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk (Solution)		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Otezla	S	Unknown	Unk		Not Reported
Apremilast	S	Unknown	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Infliximab	C	Unknown	Unk		Not Reported
Penicillin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16387991	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029881		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Voltaren Sr			S	Oral	75 Milligram,As Required		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Two Times A Day		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16388028	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029853		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Diclofenac Potassium			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Two Times A Day		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16778008	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-025000		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Diclofenac Sodium			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported

Leflunomide	C	Unknown	Not Reported
Atasol [Paracetamol]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16792776	EXPEDITED (15-DAY)		OT	PHHY2019CA209333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Ineffective; Infection	Cosentyx			S	Unknown	150 Mg, Qw		Novartis
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported
	Prednisone			C	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Q12h		Not Reported
	Xeljanz			C	Oral	5 Mg, Q12h		Not Reported
	Xeljanz			C	Oral	5 Mg, Q8h		Not Reported
	Xeljanz			C	Oral	5 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16881443	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-28961		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Remicade			S	Intravenous (not	Unknown		Not Reported

			otherwise specified)		
	Remicade	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Unknown	Unknown, Single-Use Pre-Filled Syringe	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unknown, Aerosol	Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unknown	Not Reported
	Cephalexin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17493046	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238891		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Sun
	Warfarin			S	Unknown	Unk		Taro
	Clopidogrel			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17581926	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA083381		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17584606	EXPEDITED (15-DAY)		OT	NVSC2020US082743		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	3 G, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596866	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-015777		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Aurobindo
	Dabigatran Etexilate			S	Oral	300 Milligram, Once A Day		Not Reported
	Daparox			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Valium			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported

	Folic Acid	C		1 Df, Qw	Not Reported
	Xeljanz	C		5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Prednisone	C			Not Reported
	Simponi	C	Subcutaneous	Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596898	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Folic Acid			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cetrizine			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Etanercept			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596904	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241793		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	8.22 Milligram/Kilogram		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596948	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068521		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown	20.0 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Rituxan			S	Unknown	Dosage Form: Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596980	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Methotrexate (Trade Name			S	Unknown			Not Reported

Rheumatoid Arthritis	Unknown)			
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596997	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		Unk, Qd		Sanofi
	Plaquenil			S		200 Mg, Bid		Sanofi
	Cosentyx			S		150 Mg, Q4w		Not Reported
	Humira			S		400 Mg In 7 Years		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Cymbalta			C		60 Mg, Qd		Not Reported
	Esomeprazole Magnesium;Naproxen			C	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596998	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068558		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi

Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Sulfasalazine	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Sanofi
	Mefenamic Acid	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Synthroid	C		Unk	Not Reported
	Rabeprazole Sodium	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596999	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Joint Swelling;	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi

Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Plaquenil	S	Unknown	200 Mg, Qd	Sanofi
	Plaquenil	S	Unknown	Unk	Sanofi
	Enbrel	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Ketorolac	C		Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Qw	Not Reported
	Naproxen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597002	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068605			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597003	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068651			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Methotrexate			S		20 Mg, Qow		Not Reported

Orencia	S				Not Reported
Plaquenil	S		200 Mg, Bid		Sanofi
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Bupropion	C				Not Reported
Sulfasalazine	C				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068702			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C		Unk		Not Reported
	Methotrexate			C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068717		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Leflunomide			S		Unk		Sanofi
	Allopurinol			S		Unk		Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi

	Prednisone	S		Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Naproxen	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Oxycodone Hydrochloride	S		Unk	Not Reported
	Azathioprine	S		Unk	Not Reported
	Ciclosporin	S			Not Reported
	Medroxyprogesterone Acetate	S		Unk	Not Reported
	Etanercept	S		25 Mg ,Qw	Not Reported
	Infliximab	S		400 Mg	Not Reported
	Rituximab	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597077	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1212448		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate Monosodique			S	Oral	35 Mg		Teva
	Plaquenil			S	Oral	1 Dosageform		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C		500 Mg/25 Mg,		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C				Not Reported
	Diffu K, Gelule			C				Not Reported
	Atorvastatine			C				Not Reported
	Clopidogrel (Chlorhydrate De)			C				Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597242	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025396		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, 2 Every 1 Day		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597342	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068726		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome;	Arava			S				Sanofi
	Gold Bond			S				Sanofi
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	10 Mg		Not Reported
	Plaquenil			S				Sanofi
	Arnica Montana			C				Not Reported
	Asa			C				Not Reported
	Calcium			C				Not Reported

Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Toe Amputation	Folic Acid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597343	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068740			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S		1 Df (1 Every 1 Days)		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Xeljanz			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Lyrica			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597347	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Drug Ineffective; Empyema; Foot Deformity; Hand Deformity; Joint Effusion; Joint Stiffness; Limb Operation; Musculoskeletal Stiffness; Nodule; Pneumonia; Rheumatoid Arthritis; Scar; Toe Operation	Leflunomide			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Urethral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Unknown	400 Mg		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported

Sulfasalazine	S		2000 Mg, Qd		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Calcium	C		1200 Mg		Not Reported
Ergocalciferol	C		2000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597348	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068745		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dyspepsia; Nodule; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597350	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		Unk		Sanofi
	Bacitracin			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Neomycin Sulfate			S		Unk		Not Reported
	Polymyxin B Sulfate			S		Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597351	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068446		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Arava			S		Unk Unk, Qd		Sanofi
	Meloxicam			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S		5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Paracetamol			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597410	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy Non-Responder	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg, Qd		Sanofi
	Toradol			S	Unknown			Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Qw		Not Reported
	Sulfasalazine			C		2.0 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597412	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068814		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling;	Arava			S		Unk		Sanofi

Off Label Use; Pulmonary Fibrosis; Treatment Failure	Desoximetasone		S	Oral	Unk	Sanofi
	Desoximetasone		S		Unk	Sanofi
	Leflunomide		S		1 Df, Qd	Sanofi
	Plaquenil		S		Unk	Sanofi
	Prednisone		S		Unk	Not Reported
	Hydroxychloroquine		S		200 Mg, Qd	Sanofi
	Hydroxychloroquine		S			Sanofi
	Methotrexate		S		Unk	Not Reported
	Methotrexate		S			Not Reported
	Enbrel		S		1 Df, Qw	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia		S	Subcutaneous	Unk	Not Reported
	Xeljanz		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597474	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		300 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous	Unk (Subcutaneous Solution)		Not Reported
	Alendronate Sodium			C	Oral	70 Mg		Not Reported
	Atenolol			C		3 Df		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide;Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral	40 Mg		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Lorazepam			C	Oral	1 Mg, Qd		Not Reported

Methotrexate	C		Unk		Not Reported
Sulfasalazine	C	Oral	Unk		Not Reported
Trimebutine	C		1 Df, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597475	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597476	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	40 Mg		Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	C		5 Mg, Bid		Not Reported
Xeljanz	C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597487	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597495	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069320		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			S				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597496	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S				Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Total Daily Dose 40 Mg		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597501	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597502	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069085		61 YR	Female	CAN

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

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S		Unk	Sanofi
	Actemra	S		Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Methotrexate	S			Not Reported
	Naproxen	S			Not Reported
	Naproxen Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S			Not Reported
	Prednisone Acetate	S			Not Reported
	Tocilizumab	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Folic Acid	C		Unk	Not Reported
	Hydroxychloroquine Sulphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597503	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069113		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Peripheral Swelling; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597507	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069114			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported
	Methotrexate			S	Oral	7.5 Mg 1 Every 1 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597724	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085875			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597887	EXPEDITED (15-DAY)		HO	CA-SA-2020SA069360		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598089	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020050982		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise;	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline

Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac Potassium	S	Oral	75 Mg, Prn	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Voltaren (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Glaxosmithkline
	Apo - Diclo (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Not Reported
	Apo Lisinopril	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Qd	Not Reported
	Lisinopril	S	Unknown	Unk	Not Reported
	Lisinopril Dihydrate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Synthroid	S	Oral	Unk	Not Reported
	Tecta	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598887	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Off Label Use; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571299		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599148	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020126926			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Nausea; Off Label Use; Paraesthesia; Product Use	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk (10mg To 15mg)		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer

Issue; Psoriatic Arthropathy; Rash; Rheumatoid Nodule	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	30 Mg, Unk	Pfizer
	Sulfasalazine	S	Unknown	2 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	2 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	4 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	3 G, 1x/Day	Pfizer
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cosentyx	S	Intramuscular	300 Mg, Unk	Not Reported
	Cosentyx	S	Oral	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Leflunomide	C		10 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Tocilizumab	C	Subcutaneous	162 Mg, Weekly	Not Reported
	Abatacept	C	Subcutaneous	125 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599397	NON-EXPEDITED		OT	US-APPCO PHARMA LLC-2082107			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome; Suspected Product Contamination	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600334	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026570		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600442	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076641			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Naproxen			S		Unk		Not Reported

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg Bid	Not Reported
	Prednisone	S	Oral	5 Mg Bid	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Naproxen Sodium	S		Unk	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Triamcinolone Acetonide	S		Unk (Suspension Intra-Articular)	Sanofi
	Triamcinolone Acetonide	S			Sanofi
	Triamcinolone Acetonide	S			Sanofi
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Immunoglobulins Nos	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S		5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Triamcinolone	S	Subcutaneous	25 Mg, Qow	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600446	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076650			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone	Hydroxychloroquine Sulfate			S		5 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported

Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Naproxen Sodium	S	Unknown		Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Triamcinolone Acetonide	S	Unknown		Sanofi
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S	Unknown	5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600447	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076649			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody	Hydroxychloroquine Sulfate			S	Oral	5.0 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S		5 Mg, Bid		Not Reported
	Actemra			S	Intravenous (not	280 Mg, Qow		Not Reported

Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting				otherwise specified)		
	Adalimumab		S	Subcutaneous		Not Reported
	Anakinra		S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel		S	Subcutaneous	25 Mg, Qw	Not Reported
	Enbrel		S		12.5 Mg, Qw	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	3 Mg, Qw	Not Reported
	Infliximab		S		5 Mg	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600654	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10154		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution		Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Otezla			S	Oral	Unknown		Not Reported
	Otezla			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported

	Simponi	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Penicillin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17601616	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10007		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Etanercept			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Biaxin			S	Unknown	Unknown		Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Cephalexin Monohydrate			S	Unknown	Unknown		Not Reported
	Ciprofloxacin			S	Unknown	Unknown		Not Reported
	Clindamycin Phosphate			S	Unknown	Unknown		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enalapril			S	Unknown	Unknown		Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Hctz			S	Unknown	Unknown		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unknown		Not Reported
	Levaquin			S	Unknown	Unknown		Not Reported
	Losartan			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Metoprolol Tartrate			S	Unknown	Unknown		Not Reported
	Moxifloxacin Hydrochloride			S	Unknown	Unknown		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unknown		Not Reported
	Pariet			S	Unknown	Unknown		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unknown		Not Reported

	Hydroxychloroquine	S	Unknown	Unknown		Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unknown		Not Reported
	Esomeprazole	C	Unknown	Unknown		Not Reported
	Gold	C	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unknown		Not Reported
	Iron Sucrose	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17602693	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026610		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17605425	DIRECT	Y	DE, LT			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive;	Hydroxychloroquine			S				Not Reported

Cough; Electrocardiogram Qt Prolonged; Urine Odour Abnormal	Azithromycin 250 Mg Tablet	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	15711597	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-113698		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Viread	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079854	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Duration 705		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not	Unknown		Not Reported

		otherwise specified)		
Orencia	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown. Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Gold	S	Unknown	Unknown	Not Reported
Gold	S	Intramuscular	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S			Not Reported
Apo-Azathioprine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Anakinra	S	Unknown	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079890	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06218		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased;	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported

Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Etanercept	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Abatacept	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16085223	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06099		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Infliximab			S	Intravenous (not			Not Reported

Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab	S	otherwise specified)		Not Reported
	Adalimumab	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
	Humira	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16094586	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA057581		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16788654	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA249407		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort;	Diclofenac			S	Ophthalmic	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Q12h		Not Reported
	Topicort			S	Cutaneous	Unk		Sanofi
	Prednisone			S	Oral	Unk		Not Reported

Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Prednisone	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Sanofi
	Arava	S	Oral	Unk	Sanofi
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Desoximetasone	S	Oral	Unk	Sanofi
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Sanofi
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported

Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, Qd		Not Reported
Actemra	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfathalidine	S	Oral	500 Mg		Not Reported
Sulfathalidine	S	Oral	1000 Mg, Q12h		Not Reported
Tofacitinib	S	Unknown	5 Mg, Q12h		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Q12h		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported
Atasol [Paracetamol]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16906473	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909001003			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk,		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17521215	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1193557		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Paradoxical Drug Reaction; Sleep Disorder; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4		Actavis

							Weeks			
	Azathioprine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17601958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571285			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602357	NON-EXPEDITED			US-APPCO PHARMA LLC-2082131		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Synthroid			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Olmesartan Medoxomil And Hydrochlorothiazide			C	Unknown			Not Reported
	Troujeo			C	Unknown			Not Reported
	Ezetimibe			C	Unknown			Not Reported

	Vitamin B Complex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602740	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003001986			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17603214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605175	EXPEDITED (15-DAY)		OT	CA-SA-2019SA247463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk Unk, Unk		Sanofi
	Buprenorphine			C		10 Ug, Qd		Not Reported
	Xarelto			C		15 Mg, Qd		Not Reported

Peripheral	Bisoprolol	C		12.5 Mg, Qd	Not Reported
	Lasix [Furosemide Sodium]	C		20 Mg (20mg Od/Q2days Depending On Need)	Not Reported
	Lasix [Furosemide Sodium]	C		Unk	Not Reported
	Vitamin D [Vitamin D Nos]	C		Unk	Not Reported
	Vitamin B12 Nos	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Fish Oil	C		Unk Unk, Unk	Not Reported
	Calcium	C		Unk Unk, Unk	Not Reported
	Magnesium	C		Unk Unk, Unk	Not Reported
	Ramipril	C		12.5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605363	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09913		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Cortisone	C	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Paracetamol	C	Unknown	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605416	DIRECT	Y	DE			41 YR	Male	USA

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

Acute Respiratory Distress Syndrome; Cardiac Arrest; Coronavirus Infection; Pneumonia; Renal Failure; Ventricular Tachycardia	Hydroxychloroquine		S	Oral	5 DAY	Not Reported
	Acetaminophen		C			Not Reported
	Ceftriaxone		C			Not Reported
	Cisatricurium		C			Not Reported
	Doxycycline		C			Not Reported
	Fentanyl		C			Not Reported
	Heparin		C			Not Reported
	Pantoprazole		C			Not Reported
	Midazolam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605439	DIRECT	Y	LT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tachycardia	Plaquenil			S	Oral	Other Frequency:Load - Then 200mg;		Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605541	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP009047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk. (Therapy Duration 365 Unit Unspecified)		Not Reported
	Infliximab			S	Unknown	5 Mg/Kg, One Every Eight Week		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605719	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10553		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605804	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2082143			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606206	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1212925		75 YR	Female	ITA

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

Haematochezia	Furosemide	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Teva
	Dabigatran Etexilate	S	Oral	300 Mg		Not Reported
	Daparox	S	Unknown			Not Reported
	Lamictal	S	Unknown			Not Reported
	Valium	S	Unknown			Not Reported
	Sotalol	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606630	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025455		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606828	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA085981		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive	Cosentyx			S	Unknown	Unk		Novartis

Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Oral	Unk Unk, Bid	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unknown	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	5 Mg, Bid	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Mg, Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Insulin	C	Oral	Unk	Not Reported
	Metformin	C	Unknown	2 Df, Bid	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17608508	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-015824		54 YR	Female	FRA

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

Erythema; Headache; Palpitations	Risedronate	S	Oral	35 Milligram, Total	Aurobindo
	Plaquenil	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Cortancyl	S	Oral	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Izalgi	C	Unknown	Unk	Not Reported
	Levothyrox	C	Unknown	Unk	Not Reported
	Diffu K	C	Unknown	Unk	Not Reported
	Atorvastatine	C	Unknown	Unk	Not Reported
	Clopidogrel Hydrochloride	C	Unknown	Unk	Not Reported
	Procoralan	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17611030	DIRECT	Y	DE, DS, LT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Electrocardiogram Qt Prolonged; Pneumonia Viral	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15626375	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555933-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported

Treatment Failure	Methotrexate		S	Oral	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Mobicox		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Sulfasalazine		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15712088	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588120-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous drip	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15713594	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2583819-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15738111	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594168-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Meloxicam			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16798598	EXPEDITED (15-DAY)		OT	CA-SA-2019SA250726		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S	Oral			Not Reported
	Diclofenac Sodium			S				Not Reported
	Topicort			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Sarilumab			S				Sanofi
	Sulfasalazine			S	Subcutaneous	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Desoximetasone			S				Sanofi
	Actemra			S				Not Reported
	Cortisone Acetate			S		Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	40 Mg		Not Reported
Methotrexate Sodium	S	Oral	25 Mg		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S				Not Reported
Reactine [Cetirizine Hydrochloride]	S		10 Mg, Qd		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	S				Not Reported
Leflunomide	C				Not Reported
Atasol [Paracetamol]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16805660	EXPEDITED (15-DAY)		DE	CA-TEVA-2019-CA-1108101		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown			Actavis
	Atorvastatin Calcium			S	Unknown			Teva
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva
	Metformin			S	Unknown	1000 Milligram Daily;		Not Reported
	Omeprazole Magnesium			S	Oral			Teva
	Furosemide			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported

	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17430893	NON-EXPEDITED			NVSC2020US036804			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Lymphocyte Abnormalities; Foetal Exposure During Pregnancy	Rituximab			S	Transplacental	Maternal Dose: 500 Mg/M2		Not Reported
	Azathioprine			S	Transplacental	Maternal Dose: 100 Mg, Bid		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 1 Mg/Kg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 3micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1.5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 2 Microgram/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1microgram/Kg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 10mg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 40 Mg		Not Reported
	Belimumab			S	Transplacental	Maternal Dose: Unk, Qmo		Not Reported
	Iviglob-Ex			S	Transplacental	Maternal Dose: 500 Mg/Kg		Not Reported
	Iviglob-Ex			S	Transplacental	Maternal Dose: 1000		Not Reported

				Mg/Kg	
	Iviglob-Ex	S	Transplacental	Maternal Dose: 400 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 200 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Q2w	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17432480	NON-EXPEDITED			NVSC2020US036797		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Rituximab			S	Intravenous (not otherwise specified)	500 Mg/M2		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Prednisone			S	Unknown	20 Mg, Qd		Novartis
	Prednisone			S	Oral	1 Mg/Kg Qd		Novartis
	Prednisone			S	Unknown	10 Mg Qd		Novartis
	Azathioprine			S	Unknown	100 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Romiplostim			S	Subcutaneous	3 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	1.5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	2 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	1 Microgram		Not Reported
	Belimumab			S	Unknown	Unk Unk, Qmo		Not Reported
	Dexamethasone			S	Unknown	10 Mg		Not Reported
	Dexamethasone			S	Oral	40 Mg		Not Reported
	Iviglob-Ex			S	Unknown	500 Mg/Kg		Not Reported

	Iviglob-Ex		S	Unknown	1000 Mg/Kg	Not Reported
	Iviglob-Ex		S	Unknown	400 Mg/Kg	Not Reported
	Iviglob-Ex		S	Unknown	200 Mg/Kg	Not Reported
	Iviglob-Ex		S	Unknown	500 Mg/Kg, Tiw	Not Reported
	Iviglob-Ex		S	Unknown	500 Mg/Kg, Q2w	Not Reported
	Iviglob-Ex		S	Unknown	500 Mg/Kg, Tiw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17571510	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17586904	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024281		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608636	EXPEDITED (15-DAY)		OT	FR-FERRINGPH-2020FE01903		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Menopur			S	Subcutaneous			Ferring
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608696	EXPEDITED (15-DAY)		OT	IT-BAXTER-2020BAX006523		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Diretif 10 Mg/Ml Soluzione Iniettabile			S	Unknown			Claris
	Dabigatran Etexilate			S	Oral			Not Reported

	Daparox	S	Unknown	Not Reported
	Lamictal	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Valium	S	Unknown	Not Reported
	Sotalol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608746	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001933			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterior Chamber Disorder; Blindness; Epstein-Barr Virus Infection; Eye Pain; Eye Pain; Intraocular Pressure Increased; Necrotising Retinitis; Ocular Hyperaemia; Retinal Detachment; Scleral Disorder; Uveitis; Varicella Zoster Virus Infection; Vision Blurred; Vitreous Floaters; Vitritis	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Cellcept			S	Unknown	1000 Mg, Bid		Not Reported
	Valacyclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608765	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1216776			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Atorvastatin			S				Teva
	Methotrexate			S				Barr
	Plaquenil			S		400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alprazolam			C				Not Reported
	Folic Acid			C				Not Reported
	Naprosyn			C		1000 Milligram Daily;		Not Reported

	Pantoloc	C			Not Reported
	Prednisone	C	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608937	EXPEDITED (15-DAY)		DS, HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000912			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Dyspnoea; Left Ventricular Dysfunction	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Qd		Ipca
	Fexofenadine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Novo Nordisk Pharms Novofem			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Hyoscine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609386	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA086791		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Meperidine Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Novartis
	Bisoprolol			S	Unknown	Unk		Novartis
	Levofloxacin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Oral	20 Mg, Qw		Not Reported
Arava	S	Unknown	Unk		Not Reported
Arthrotec	S	Unknown	Unk		Not Reported
Ceclor	S	Unknown	Unk		Not Reported
Celebrex	S	Oral	200 Mg, Qd		Not Reported
Demerol	S	Unknown	Unk		Not Reported
Erythromycin	S	Unknown	Unk		Not Reported
Erythromycin Estolate	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	400 Mg		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Metronidazole	S	Unknown	5 Mg		Not Reported
Norfloxacin	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	400 Mg, Qd		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609994	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-177659		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610209	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020050661		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Furosemide			S	Unknown	Unk		Glaxosmithkline

	Daparox	S	Unknown	Unk		Glaxosmithkline
	Valium	S	Unknown	Unk		Glaxosmithkline
	Plaquenil	S	Unknown	Unk		Not Reported
	Dabigatran Etexilate	S	Oral	300 Mg, Qd		Not Reported
	Sotalol	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610630	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026351		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2 Weeks		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 1 Every 2 Weeks		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1every One Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Benadryl [Diphenhydramine			C	Unknown	Unk		Not Reported

Hydrochloride]					
Naproxen	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Viread	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611049	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09980			Female	CAN

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

	Rituxan	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611066	DIRECT	Y	DS, OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Immunosuppressant Drug Level Increased	Plaquenil			S				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611141	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611326	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611609	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10259			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported

Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gold		S	Unknown	Unknown	Not Reported
	Humira		S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral	Unknown	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Unknown	Unknown	Not Reported
	Plaquenil		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Unknown	Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611785	EXPEDITED (15-DAY)		OT	IT-VALIDUS PHARMACEUTICALS LLC-IT-2020VAL000236			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Sotalol Hydrochloride			S	Unknown	Unk		Not Reported
	Dabigatran			S	Oral	Unk		Not Reported

	Daparox /00830803/			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17614765	DIRECT	Y	DE, LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Cytokine Storm; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	Other Dose:400-200 Mg;		Not Reported
	Haldol			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cistaracurijm			C				Not Reported
	Docusate Sodium			C				Not Reported
	Exoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Versed			C				Not Reported
	Propofol Continuous Infusion			C				Not Reported
	Pantoprazole			C				Not Reported
	Sennosides			C				Not Reported
	Sertraline			C				Not Reported
	Darunavir/Cobistat			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin			C				Not Reported
	Donepezil			C				Not Reported
	Ketoconazole 2% Shampoo			C				Not Reported
	Nitroglycerin Sl			C				Not Reported
	Sertrraline			C				Not Reported
	Sevelamer			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	14217330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025441		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Remicade	S				Not Reported
Methotrexate	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16568503	EXPEDITED (15-DAY)		HO, OT	PHHY2019PL128630		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn	Erelzi			S	Intravenous (not otherwise specified)	50 Mg, Unk		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	10 Mg, Qd		Not Reported
	Encorton			S	Unknown	15 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	20 Mg, Qd		Not Reported
	Insulin			C	Unknown	Unk		Not Reported

	Metex		C	Subcutaneous	Unk (The Last Injection In Jan-2019)	Not Reported
	Metex		C	Subcutaneous	Unk (The Last Injection In Jan-2019)	Not Reported
	Folic		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16820135	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201804-001105			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Fatigue; Hepatomegaly; Malaise; Nausea; Pain In Extremity; Puncture Site Pain; Rash; Splenomegaly; Systemic Lupus Erythematosus; Vein Disorder; Vessel Puncture Site Bruise; Vessel Puncture Site Swelling	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Cerezyme			S	Intravenous drip	Dose/Unit: 3200.00 Frequency: Q2		Not Reported
	Cerezyme			S	Intravenous (not otherwise specified)	3200 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17575062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609231	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002203			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609364	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002205			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609365	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002204			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611781	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611782	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002280			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611783	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002281			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17613937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2572186			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614080	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202003002074			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Organ Transplant; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk (For Over 30 Years)		Concordia
	Cellcept			S	Unknown	500 Mg, Tid (For 1.5 Years)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614116	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported

Rituximab	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614240	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0121425			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Trichlormethiazide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614467	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026601		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling;	Orencia			S	Unknown			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Milligram, Tid		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616393	DIRECT					63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Vertigo	Hydroxychloroquine 200 Mg Tablets			S	Oral	Quantity:180 Tablet(S);		Zydus Pharm
	Norvas			C				Not Reported
	Hctz			C				Not Reported
	Potassium Chloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Predinsdone			C				Not Reported
	Pravastatin			C				Not Reported
	General Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616524	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS		65 YR	Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Cat Scratch Disease; Complication Associated With Device	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Westward
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616629	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Visual Impairment	Hydroxychloroquine			S		Quantity:1 Tablet(S);		Sandoz
	Valsartan			C				Not Reported
	Metoprolol			C				Not Reported
	Atorvastatin			C				Not Reported
	Levothyroxine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Apsirin			C				Not Reported
	Women'S Silver Centrum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616815	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Hydroxychloroquine			S	Oral			American Health
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616895	EXPEDITED (15-DAY)		OT	NVSC2020GB089786		43 YR	Female	GBR

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

Chronic Cutaneous Lupus Erythematosus; Cutaneous Lupus Erythematosus; Disease Progression; Madarosis; Mucosal Pain; Product Use In Unapproved Indication; Skin Plaque	Mycophenolate Mofetil		S	Unknown	1 G, Bid	Novartis
	Hydroxychloroquine		S	Transdermal	200 Mg, Qd	Not Reported
	Tacrolimus		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17618200	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3348747-00		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 100/25			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17629156	DIRECT	Y				22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine			S	Subcutaneous			Abbvie
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	12994284	EXPEDITED (15-DAY)		OT	CA-SA-2016SA199672		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Qw		Not Reported

Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Sulfasalazine		C	Unknown	1 G, Bid	Not Reported
	Celebrex		C	Unknown	Unk Unk,Unk	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	13660454	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1724612US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Cyclical		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Qd		Not Reported
	Risedronic Acid			S	Unknown	Unk		Not Reported
	Risedronic Acid			S	Unknown	35 Mg, Q Week		Not Reported
	Risedronic Acid			S	Unknown	35 Mg, Q Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15108418	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0726		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Kineret			S	Unknown			Not Reported

Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Arava		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Meloxicam		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15619709	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555775-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15620439	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556971-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Rheumatoid Arthritis	Apo-Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15994348	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2674858-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16567681	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Sodium			S	Unknown	150 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown	400 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Piroxicam			C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16687965	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210544		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Arava			S		366 Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Pregabalin			S		150 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Orencia			S		Unk		Not Reported

	Orencia	S			Not Reported
	Xeljanz	S		Unk	Not Reported
	Rituxan	S		1000 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	1000 Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Trazodone	C		200 Mg, Qd	Not Reported
	Lumigan Rc	C	Ophthalmic	1 Df, Qd	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C		10 Mg, Qd	Not Reported
	Tylenol [Paracetamol]	C		Unk	Not Reported
	Tylenol [Paracetamol]	C		3000 Mg, Qd	Not Reported
	Valsartan	C		1 Df, Qd	Not Reported
	Valsartan	C		Unk	Not Reported
	Wellbutrin	C		300 Mg, Qd	Not Reported
	Esomeprazole	C		40 Mg, Qd	Not Reported
	Nexium [Esomeprazole Sodium]	C		40 Mg, Qd	Not Reported
	Tylenol Extra Strength	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16720242	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Arava			S	Oral	10 Mg, Qd		Sanofi
	Diclofenac			S	Unknown	50 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Prior To 2011)		Sanofi
	Indometacin			S		50 Mg, (20 To 50 Mg) Tid		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd (Prior To 2016)		Sanofi

Methotrexate	S	Oral	10 Mg, Qw		Not Reported
Methotrexate	S	Oral	15 Mg, (10 To 15 Mg) Qw (Prior To 2011)		Not Reported
Naproxen	S	Unknown	500 Mg, Q6h		Not Reported
Plaquenil	S	Unknown	Unk		Sanofi
Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17199927	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3206389-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17559777	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17571111	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008956		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Q.O.Wk.		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Unk		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk, 1 Every 4 Weeks		Not Reported
	Orencia			S	Unknown	500 Mg, Unk, 1 Every 4 Weeks		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17575454	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008927		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	200 Mg, Qd		Apotex

Methotrexate	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Arava	C	Unknown	20 Mg, Qd		Not Reported
Simponi	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611780	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002282			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611784	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002283			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611792	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17618992	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001932			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Injury; Fatigue; Headache; Therapeutic Response Delayed; Therapeutic Response Shortened; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk (Or, Dose, Frequency, Route Lot Number And Expiry Date Unknown)		Not Reported
	Actemra			S	Unknown	Unk (Suspended On 25-Feb-2020)		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Pantoloc			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17619006	EXPEDITED (15-DAY)		DS	CA-ADVANZ PHARMA-202003001934			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Liver Disorder; Loss Of Personal Independence In Daily Activities; Oral Herpes	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Voltaren			C		Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622122	EXPEDITED (15-DAY)		OT	CA-ROCHE-2573031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg Was Reduced To 7.5 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217045		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Celecoxib			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Unknown			Teva
	Pregabalin			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride/Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported

Apo-Azathioprine	S	Unknown		Not Reported
Apo-Diclofenac	S	Topical		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	7.1429 Milligram Daily;	Not Reported
Etanercept	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S			Not Reported
Misoprostol	S	Unknown		Not Reported
Naprosyn [Naproxen	S	Unknown		Not Reported
Nifedipine	S	Unknown		Not Reported
Orencia	S	Subcutaneous	107.1429 Milligram Daily;	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Winpred	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Tofacitinib	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram Daily;		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA079660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Codeine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported

	Humira	C	Not Reported
	Orencia	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622915	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pancytopenia	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623040	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623288	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05347		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Advil			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported

	Ketorolac	C	Unknown	Unknown		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Naproxen	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623349	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1578		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624098	EXPEDITED (15-DAY)		HO, OT	NVSC2020US090011		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cardiomyopathy; Cardiotoxicity; Dyspnoea Exertional; Orthopnoea; Peripheral Swelling	Hydroxychloroquine			S	Unknown	200 Unk, Bid		Novartis
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624253	EXPEDITED (15-DAY)		OT	CA-EMD SERONO-E2B_90076287		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin Hydrochloride			S	Unknown	Unknown		Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Cymbalta			S	Unknown	Unknown Dosage		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Imuran /00001501/			C	Unknown	Unknown		Not Reported
	Xarelto			C	Unknown	Unknown		Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624589	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-009614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Oral			Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625486	EXPEDITED (15-DAY)		HO, LT, OT	MX-ACCORD-178039		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Off Label Use; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolic Acid			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625490	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-242736		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, In Total		Sun
	Plaquenil			S	Oral	1 Dosage Form, Daily		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral	()		Not Reported
	Pantoprazole			C	Unknown	()		Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C	Unknown	()		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C	Unknown	()		Not Reported
	Diffu K, Gelule			C	Unknown	()		Not Reported
	Atorvastatine			C	Unknown	()		Not Reported
	Clopidogrel (Chlorhydrate De)			C	Unknown	()		Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625695	EXPEDITED (15-DAY)		DE	IE-ABBVIE-20K-229-3352301-00		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Mabthera			S	Unknown			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Seroquel			C				Not Reported
	Arava			C				Not Reported
	Depo-Medrone			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Methotrexate			C				Not Reported
	Protium			C				Not Reported
	Valdoxan			C				Not Reported
	Alendronate			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Prednisolone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625752	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217530		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15674250	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573605-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthritis; Synovitis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			C				Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15702726	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580931-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Celebrex		C			Not Reported
					Lyrica		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15733752	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594187-00		65 YR	Female	CAN

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

	Minocycline	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Xeljanz	C	Unknown	Not Reported
	Hydroxychloroquine	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15734078	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594192-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16040473	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1020190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Meloxicam			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16301153	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16381114	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2804954-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Unevaluable Event; Urticaria	Leflunomide	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Amlodipine	C		Not Reported
	Arava	C		Not Reported
	Benadryl	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Viread	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16441274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822469-00		65 YR	Female	CAN

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

	Lyrica	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16443280	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2819775-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16497972	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026465			Female	CAN

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

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Cimzia	S	Subcutaneous		Not Reported
	Acetaminophen	S	Endocervical		Not Reported
	Actemra	S			Not Reported
	Arava	S		20 Milligram, Once Daily (Qd)	Not Reported
	Arava	S		10 Milligram, Once Daily (Qd)	Not Reported
	Enbrel	S		50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
	Methotrexate	C		Unk, Weekly (Qw)	Not Reported
	Meloxicam	C			Not Reported
	Synthroid	C			Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Apo-Prednisone	S	Oral	20 Nanogram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Codeine	C			Not Reported
	Tylenol [Paracetamol]	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16714535	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16717736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216698		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebral Disorder; Condition Aggravated; Cystitis; Disturbance In Attention; Drug Intolerance; Gait Disturbance; Grip Strength Decreased; Hypersensitivity; Intentional Product Use Issue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased;	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Oral	400 Mg 3-4/Day		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Hydroxychloroquine			S				Sanofi
	Gold			S	Intramuscular	10 Mg, 1x		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

Musculoskeletal Stiffness; Pneumonitis; Therapeutic Product Effect Incomplete

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17156996	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Janssen
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17200098	EXPEDITED (15-DAY)		OT	SE-ADVANZ PHARMA-201912003018			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Lupus Erythematosus; Drug Ineffective	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid ,1 Tablet Twice A Day For 2 Weeks		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form		Concordia
	Trombyl			C		75 Mg		Not Reported
	Candesartan			C		16 Mg		Not Reported
	Levaxin			C		25 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Dermovate			C		Unk		Not Reported
	Omeprazol			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17350398	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		25 Milligram, Weekly (Qw)		Not Reported
	Leflunomide			S				Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S		1 Gram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram, Once Daily (Qd)		Not Reported
	Xeljanz			C		5 Milligram, 2x/Day (Bid)		Not Reported
	Xeljanz			C		11 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17563093	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Alopecia; Amnesia; Contraindicated Product Administered; Delirium; Diabetes Mellitus;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Gait Disturbance; Glossodynia; Grip Strength Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Maternal Exposure During Pregnancy; Mobility Decreased; Muscular Weakness; No Adverse Event; Pain; Pain In Extremity; Pemphigus; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Walking Aid User; Weight Decreased; Wound Infection	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Cosentyx	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride W/Tri/00005601/	S	Unknown	Not Reported
	Reactine /00884302/	S	Unknown	Not Reported
	Naprosyn /00256201/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628438	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202003002241			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fibromyalgia; Malaise; Pleural Effusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form,Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628439	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002041			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	Unk, (Coated Tablets)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628622	EXPEDITED (15-DAY)		DS, OT	FR-ADVANZ PHARMA-202003002294			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Chronic Obstructive Pulmonary Disease; Diabetes Mellitus; Infection; Pneumonia; Respiratory Distress; Wheelchair User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia
	Cortancyl			C		Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C		Unk		Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628632	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3352546-00			Female	CAN

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

Drug Hypersensitivity; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628958	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014088		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oral Pain; Oropharyngeal Pain; Stomatitis	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Subcutaneous	200 Milligram		Not Reported
	Benzylhydrochlorothiazide			C				Not Reported
	Coumadin			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Eltroxin			C				Not Reported
	Metoprolol			C				Not Reported
	Pravachol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr

	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629303	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217500		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629306	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629352	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217523			Female	CAN

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

Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Depo-Medrol	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629366	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate			S	Oral				Not Reported
	Sulfasalazine			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629396	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217963		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629398	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Actemra			S	Subcutaneous	23.1429 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
Kevzara	S	Subcutaneous			Not Reported
Sodium Aurothiomalate	S	Parenteral			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Esomeprazole	C	Unknown			Not Reported
Magnesium	C	Unknown			Not Reported
Metformin	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629497	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001847			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Decreased; Drug Tolerance Increased; Hypoacusis; Joint Injury; Joint Swelling; Migraine; Musculoskeletal Disorder; Therapeutic Product Effect Decreased; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid, One In The Morning One In Night		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629815	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002043			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Shortened Cervix	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17630225	EXPEDITED (15-DAY)		OT	NVSC2020CA090993			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	10 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631124	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3352969-00		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral	200 Mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631943	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217985		63 YR	Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632099	NON-EXPEDITED		OT	NVSC2020US092034		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Diastolic Dysfunction	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632120	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217560			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling;	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S		20 Millimol Daily;		Not Reported

Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632212	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014049		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Arava			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Cephalexin Monohydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632213	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014044		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder;	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S				Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly (Qw)		Not Reported
	Glumetza			S		500 Milligram, 2x/Day		Not Reported

Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased				(Bid)		
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S				Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Lyrica	S	Oral			Not Reported
	Methotrexate	S				Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S				Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Acetaminophen	C				Not Reported
	Altace	C				Not Reported
	Arava	C				Not Reported
	Asa	C				Not Reported
	Codeine	C				Not Reported
	D-Alpha Tocopherol	C				Not Reported
	Ergocalciferol	C				Not Reported
	Folic Acid	C				Not Reported
	Prednisone	C	Oral			Not Reported
	Rosuvastatin Calcium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Erythematosus	Actemra		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632341	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632490	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-2014318US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate Sodium Unk			S	Oral	35 Mg, Q Week		Allergan
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Not Reported
	Mycophenolate Mofetil			S	Oral	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd		Not Reported
	Azathioprine			C	Oral	50 Mg, Qd		Not Reported
	Azathioprine			C	Oral	150 Mg, Qd		Not Reported
	Azathioprine			C	Oral	100 Mg, Bid		Not Reported
	Humira			C	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Ketoprofen			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q Week		Not Reported
	Prolia			C	Subcutaneous	Actual: 60 Mg, Every 6 Months		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632612	EXPEDITED (15-DAY)		OT	CA-SA-2020SA073892			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217558			Female	CAN

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

Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam	S	Oral		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	2.8571 Milligram Daily;	Not Reported
	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633310	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217525		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown	22.8571 Milligram Daily;		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Arava	S	Unknown	200 Milligram Daily;	Not Reported
	Actemra	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol			C				Not Reported
	Diclofenac			C				Not Reported
	Humira			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	14299100	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050873			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17257461	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020AU004219			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver	Mycophenolate Mofetil			S	Oral	500 Mg, Tid		Novartis
	Mycophenolate Mofetil			S				Novartis
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported

Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Methotrexate	S	Subcutaneous	10 Unk, Biw (Mcg)	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
	Rosuvastatin	S	Unknown	10 Mg	Not Reported
	Ezetimibe	S	Unknown	10 Mg	Not Reported
	Ramipril	S	Unknown	Unk Mg, Unknown (5-10)	Not Reported
	Topiramate	S	Unknown	200 Mg, Unknown	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	5-Methyltetrahydrofolate	S	Unknown	Unk	Not Reported
	Oxycontin	S	Oral	10 Mg, Bid	Not Reported
	Endone	S	Oral	5 Mg, Qd	Not Reported
	Aspirin	S	Unknown	100 Mg, Unknown	Not Reported
	Prasugrel	S	Unknown	10 Mg, Qd	Not Reported
	Ivabradine	S	Unknown	7.5 Mg, Bid	Not Reported
	Sildenafil	S	Oral	12.5 Mg, Prn	Not Reported
	Gtn	S	Oral	Unk	Not Reported
	Cannabis Sativa Oil	S	Unknown	Unk	Not Reported
	Reboxetine	S	Unknown	4 Mg, Bid	Not Reported
	Cholecalciferol	S	Unknown	50 Unk, Qd (Mcg)	Not Reported
	Novorapid	S	Subcutaneous	Unk (Pump With Continuous Bgl Monitor)	Not Reported
	Glucagen Hypokit	S	Unknown	Unk	Not Reported
	Mirena	S	Unknown	52 Mg, Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Biw	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17374357	NON-EXPEDITED			US-PFIZER INC-		64 YR	Female	USA

2020048790

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557586	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318928		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17577750	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596897	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068369		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068453			Female	CAN

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

Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S		Unk	Sanofi
	Prednisone	S		Unk	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cortisone Acetate	S		Unk	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Alendronate Sodium	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Sanofi
	Methotrexate	S		Unk	Not Reported
	Plaquenil	S		Unk	Sanofi
	Pseudoephedrine Hydrochloride	S		Unk	Sanofi
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Actemra	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597473	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068824		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Shoulder Operation;	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Therapeutic Response Decreased	Methotrexate	S			Not Reported
	Orencia	S			Not Reported
	Sulfasalazine	S			Not Reported
	Cymbalta	C			Not Reported
	Hydromorphone	C			Not Reported
	Hydromorph Contin	C			Not Reported
	Lyrica	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597488	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068873		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg		Sanofi
	Methotrexate			S	Unknown	5 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608427	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatitis; Hypersensitivity;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Endocervical	Unk		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Inflammatory Marker Increased; Keratitis; Off Label Use; Skin Reaction; Synovitis; Thyroid Cancer	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Etanercept	S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Aspirin /00002701/	C	Unknown	Unk	Not Reported
	Avapro	C	Unknown	Unk	Not Reported
	Biaxin	C	Unknown	Unk	Not Reported
	Humalog	C	Unknown	Unk	Not Reported
	Insulin	C	Oral	Unk	Not Reported
	Lantus	C	Unknown	Unk	Not Reported
	Metformin Hydrochloride	C	Unknown	Unk	Not Reported
	Nystatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608759	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202002001099			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Platelet Count Decreased; Red Blood Cell Count Decreased; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Imiquimod			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635250	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014082		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported

Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S			Not Reported
	Hydroxychloroquine Sulfate		S			Not Reported
	Leflunomide		S			Not Reported
	Methotrexate		S		25 Milligram, Once Daily (Qd)	Not Reported
	Orencia		S			Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution For Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635999	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636295	EXPEDITED (15-DAY)		LT	NVSC2020US090949			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Near Death Experience	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Benadryl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636540	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219972		54 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	20 Mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	400mg/12h Dia 1 Seguido De 200mg/12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636766	EXPEDITED (15-DAY)		OT	CA-SA-2020SA085603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Topicort			S	Topical			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Prednisone			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029039		37 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637833	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219073		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638187	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219970		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400mg / 12h Day 1 Followed By 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638596	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK047124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural	Gabapentin			S	Unknown	100 Milligram, Bid		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram; 1 Every 1 Month		Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3		Not Reported

Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure				Week	
	Myochrysine	S	Intramuscular	50 Milligram; 1 Every 3 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw (1 Every 1 Week)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qw (1 Every 1 Week)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid (2 Every 1 Day)	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk, Od	Not Reported
	Ergocalciferol	C	Unknown	Unk, Od (1 Every 1 Day)	Not Reported
	Ergocalciferol	C	Unknown	400 Iu International Unit(S), Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid (2 Every 1 Day)	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Milligram, Unk	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Od	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram, Unk	Not Reported
	Prednisone	C	Unknown	5.0 Gigabecquerel, Od	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported

Risedronate Sodium	C	Unknown	36 Milligram, Qw (1 Every 1 Week)	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Od	Not Reported
Tylenol /00020001/	C	Unknown	1000 Milligram, Qd	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638618	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219180		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638655	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218933		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling;	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218942		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Overlap Syndrome; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639284	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported

Fibrosis; Therapeutic Response Decreased	Methotrexate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639471	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001059			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiomyopathy; Cutaneous Lupus Erythematosus; Neutropenia; Renal Failure; Retinal Injury; Thrombocytopenia; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641570	EXPEDITED (15-DAY)		OT	NVSC2020US094182		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641778	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15738004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2595168-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16575509	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852070-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychoroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Vitamin D3			C				Not Reported
	Ergocalciferol			C				Not Reported
	Colecalciferol			C				Not Reported
	Imuran			C				Not Reported
	Gold			C				Not Reported
	Arthrotec			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16864058	EXPEDITED (15-DAY)		OT	DE-GILEAD-2019-0424518			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect	Ambrisentan			S	Unknown	Unk		Gilead
	Roactemra			S	Unknown	162 Mg, Z(Weekly)		Not Reported
	Quensyl			S	Unknown	20 Mg, Bid		Not Reported
	Ramipril			S	Unknown	2.5 Mg, Bid		Not Reported
	Spasmolyt			S	Unknown	15 Mg, Qd		Not Reported

Incomplete; Therapy Cessation; Visual Impairment	Eliquis	S	Unknown	2.5 Mg, Bid		Not Reported
	Eliquis	S	Unknown	1 Dosage Form		Not Reported
	Omeprazole	S	Unknown	20 Mg, Bid		Not Reported
	Lyrica	C	Unknown	100 Mg, Tid		Not Reported
	Pregabalin	S	Unknown	100 Mg, Tid		Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16991114	EXPEDITED (15-DAY)		OT	CA-SA-2019SA303996			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S				Sanofi
	Pseudoephedrine Hydrochloride			S				Sanofi
	Sulfasalazine			S		500 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported

Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Methotrexate Sodium	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Phthalylsulfathiazole	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S				Not Reported
Apo Prednison	S				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17579771	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327850		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17583352	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024371		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported

Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Pregabalin	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587303	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329619			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587307	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327870		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17605637	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333273		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17641623	EXPEDITED (15-DAY)		HO, OT	EG-ADVANZ PHARMA-202003002270			Unknown	EGY

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

Atrial Fibrillation; Blindness; Blood Glucose Abnormal; Brain Oedema; Loss Of Consciousness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	2 Dosage Form, Qd		Concordia
	Insulin	C		30 Iu, Qd		Not Reported
	Menthol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17642134	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002077			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Surgery; Pain	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644154	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1220064		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12 Day 1 Followed By 200 Mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644417	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002359			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645665	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1655		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-	Anakinra			S	Subcutaneous			Not Reported

Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Actemra	S			Not Reported
	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S	Oral		Not Reported
	Azathioprine Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Gold	S	Intramuscular		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Penicillamine	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Docusate Sodium	C	Oral		Not Reported
	Elavil	C	Unknown		Not Reported
	Tobramycin	C	Unknown	0.3% 4x1 Daily	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
	Doxycycline	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Sulfasalazine	C	Oral	1.5 G 2x1 Daily	Not Reported

Sulfasalazine	C	Unknown		Not Reported
Wellbutrin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645727	NON-EXPEDITED			NVSC2020US094449		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646286	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646292	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646454	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002357			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Off Label Use; Prostatic Adenoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028979		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17647436	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356481-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Sodium Aurothiomalate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356478-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not	300 Milligram, Q6wk		Not Reported

		otherwise specified)	
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649456	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Oseltamivir Phosphate			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Sodium Chloride 0.9% 1000 Ml			C				Not Reported
	Azithromycin 500 Mg			C				Not Reported
	Zosyn 3.375 G			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Atropine			C				Not Reported
	Epinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649584	NON-EXPEDITED			US-TEVA-2020-US-1213903			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649858	NON-EXPEDITED			NVSC2020US093707			Male	USA

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

Abdominal Discomfort	Hydroxychloroquine Sulfate		S	Unknown	Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651063	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651159	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029452			Female	CAN

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

Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia	S	Unknown			Bristol Myers Squibb
	Sulfasalazine	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown			Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Lyrica	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Humira	S	Unknown	40 Milligram		Not Reported
	Enbrel	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Piroxicam	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651582	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15219753	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-NODEN PHARMA DAC-NOD-2018-000052			Female	DEU

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

Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Noden Pharma
	Rasilez	S			Noden Pharma
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Prednisolone	S	Transplacental	Unk	Not Reported
	Salbutamol Sulfate	S	Transplacental	Unk, If Required; Trimester: First+Second;From Gestational Week 0-14	Not Reported
	Salbutamol Sulfate	S	Transplacental	Unk	Not Reported
	Delix /00885601/	S	Transplacental	Maternal Dose 20 Mg, Qd (Exposure Duration 0-13+6 Weeks)	Not Reported
	Delix /00885601/	S			Not Reported
	Quensyl	S	Transplacental	400 [Mg/D (2x200)]; 0-13.6 Gestational Week;From Gestational Week 0-14	Not Reported
	Quensyl	S	Transplacental	Unk	Not Reported
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
	Acetylsalicylic Acid	S			Not Reported
	Pantozol /01263204/	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week;From Gestational Week 0-14 (Busco Pantoprazole)	Not Reported
	Pantozol /01263204/	S	Transplacental	Unk	Not Reported
	Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Torasemide	S	Transplacental	Unk	Not Reported
	Advagraf	S	Transplacental	6 [Mg/D]; 0-13.6 Gestational Week, From Gestational Week 0-14	Not Reported

Advagraf	S	Transplacental	Unk	Not Reported
Advagraf	S			Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	Unk	Not Reported
Ezetimibe Msd	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Exposure Duration: 0-14 Weeks. Trimester: First; Probably Only In Hospital In Week 5.	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Novaminsulfon	S	Transplacental	300 Milligram, Qd	Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Clexane	S			Not Reported
Heparin Lmw	S	Transplacental	Unknown	Not Reported
Heparin Lmw	S			Not Reported
Enoxaparin	S	Transplacental	From Gestational Week 0-14	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Rituximab	S	Transplacental	Unk	Not Reported
Heparin	S	Transplacental	Unk (Low Molecular Weight Heparin)	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

	Mifegyne		C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Cyclophosphamide		C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
	Cyclophosphamide		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15551940	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-967934			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Actavis
	Torem			S	Transplacental	100 [Mg/D]		Not Reported
	Quensyl			S	Transplacental	200 Milligram Daily; Daily Dose: 400 Mg Millgram(S) Every Days		Not Reported
	Rituximab			S	Transplacental	Last Time In December 2011: Pre Or Periconceptional		Not Reported
	Inegy			S	Transplacental	40 [Mg/D] / 10 [Mg/D]		Not Reported
	Delix (Ramipril)			S	Transplacental	20 [Mg/D]		Not Reported
	Advagraf			S	Transplacental	6 [Mg/D]		Not Reported
	Pantozol			C	Transplacental	40 [Mg/D]		Not Reported
	Albuterol			C	Transplacental	Unk, Prn		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported
	Cyclophosphamid			C	Transplacental	3000 [Mg Cumulative]/ April -August 2011		Not Reported
	Xarelto 10 Mg Filmtabletten			C	Transplacental	Not Known, If Treatment Started Before Or After Missed Abortion.		Not Reported
	Clexane			C	Transplacental	200 [Mg/D (2x100)]		Not Reported
	Novaminsulfon			C	Unknown	For 5 Weeks		Not Reported
	Aliskiren			C	Transplacental	300 [Mg/D]		Not Reported

Mifegyne	C	Transplacental	Unk		Not Reported
Rasilez	C	Transplacental	300 [Mg/D]		Not Reported
Salbutamol	C	Transplacental	If Required		Not Reported
Prednisolon	C	Transplacental	Daily Dose: 10 Mg Milligram(S) Every 2 Day		Not Reported
Ass	C	Transplacental	100 [Mg/D]		Not Reported
Novaminsulfon	C	Transplacental	Probably Only In Hospital In Week 5		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15635156	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105525		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Gram, Q2wk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	2000 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	Unk Unk, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605642	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332799		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17647143	EXPEDITED (15-DAY)		HO, LT, OT	MX-ALKEM LABORATORIES LIMITED-MX-ALKEM-2020-01066		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram, Qd		Alkem
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
	Prednisone			S	Oral	30 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648078	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		75 YR	Female	CAN

BMS-2020-029659

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk Unk, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk, Qd		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Minocycline			C	Unknown	Unk		Not Reported
	Penicillamine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648606	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029670		56 YR	Female	CAN

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

Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Orencia	S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Actemra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qh	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	175 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate Sodium	S	Unknown	35 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Milligram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Risedronate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648737	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2020061233		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome;	Ceftriaxone Sodium			S	Unknown	Unk		Glaxosmithkline
	Streptomycin			S	Unknown	Unk		Glaxosmithkline
	Cotrimoxazole			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline

Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Sulfamethoxazole + Trimethoprim	S	Unknown	960 Mg, Qd	Glaxosmithkline
	Ceftriaxone	S	Unknown	Unk	Glaxosmithkline
	Azathioprine	S	Unknown	Unk	Glaxosmithkline
	Acyclovir	S	Unknown	Every 4 Hours.	Glaxosmithkline
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Dose Increased	Not Reported
	Prednisone	S	Unknown	Dose Reduced	Not Reported
	Doxycycline	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648841	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202003002755			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17649603	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1219671		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal	Gabapentin			S	Oral			Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;	Not Reported
	Acetaminophen	C			Not Reported
	Aclasta	C			Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid	C			Not Reported
	Nasonex	C			Not Reported
	Prednisone	C			Not Reported
	Trazodone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17651306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Subcutaneous			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652025	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202003002774			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652041	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000624			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Xarelto			C		Unk		Not Reported
	Vitamin B12 Nos			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported

	Bisoprolol	C	Unk	Not Reported
	Fish Oil	C	Unk	Not Reported
	Magnesium	C	Unk	Not Reported
	Ramipril	C	Unk	Not Reported
	Buprenorphine	C	Unk	Not Reported
	Vitamin D	C	Unk	Not Reported
	Xeljanz	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Vitamin B6	C	Unk	Not Reported
	Arava	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652062	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1220063		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Unknown	200 Milligram Daily;		Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram Daily;		Not Reported
	Aclasta			C	Intravenous (not			Not Reported

		otherwise specified)		
Ascorbic Acid	C	Unknown		Not Reported
Biotin	C			Not Reported
D-Alpha Tocopherol	C	Unknown	2400 Milligram Daily;	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram Daily;	Not Reported
Diphenoxylate Hydrochloride	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	400 Iu (International Unit) Daily;	Not Reported
Esomeprazole	C	Unknown	80 Milligram Daily;	Not Reported
Ferrous Fumarate	C	Unknown		Not Reported
Folic Acid	C			Not Reported
Hydroxocobalamin	C			Not Reported
Loperamide Hydrochloride	C	Unknown		Not Reported
Nasonex	C	Unknown	4 Dosage Forms Daily;	Not Reported
Nicotinamide	C			Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram Daily;	Not Reported
Nortriptyline Hydrochloride	C	Oral		Not Reported
Prednisone	C	Unknown	5 Gbq Daily;	Not Reported
Pyridoxine Hydrochloride	C			Not Reported
Riboflavin	C			Not Reported
Risedronate Sodium	C	Unknown		Not Reported
Sodium Ascorbate	C			Not Reported
Thiamine Hydrochloride	C			Not Reported
Thiamine Mononitrate	C			Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram Daily;	Not Reported
Tylenol	C	Unknown	1000 Milligram Daily;	Not Reported
Vitamin A	C			Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported
Vitamin D3	C			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17654933	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Endotracheal Intubation Complication	Hydroxychloroquine			S	Oral			Teva
	Hydroxychloroquine			S	Oral			Teva
	Azithromycin			C				Not Reported
	Albuterol			C				Not Reported
	Lasix			C				Not Reported
	Zosyn			C				Not Reported
	Humulin R			C				Not Reported
	Vancomycin			C				Not Reported
	Lovenox			C				Not Reported
	Tamiflu			C				Not Reported
	Rocephin			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran			C				Not Reported
	Ns			C				Not Reported
	D50w			C				Not Reported
	Pravachol			C				Not Reported
	Ativan			C				Not Reported
	Doxycycline			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	16946977	EXPEDITED (15-DAY)		LT, OT	CA-GLAXOSMITHKLINE-CA2019AMR190534		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Fatigue; Off Label Use; Suicidal Ideation	Benlysta			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		200 Mg		Glaxosmithkline

	Benlysta	S	Subcutaneous	Unk		Glaxosmithkline
	Imuran	S	Oral	200 Mg, Qd		Glaxosmithkline
	Plaquenil	S		400 Mg, Qd		Not Reported
	Prednisone	S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17395563	NON-EXPEDITED			US-AMGEN-USASP2020020542		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653559	NON-EXPEDITED		OT	US-SA-2020SA089843			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Arava			S				Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653880	EXPEDITED (15-DAY)		DE	FR-TEVA-2020-FR-1221561		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Ebilfumin 75 Mg, Gélule			S	Oral	75 Mg		Teva
	Ceftriaxone Mylan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Plaquenil			S	Oral	At D1 Then 400mg / Day, Unit Dose: 800 Mg		Not Reported
	Coversyl 5 Mg, Comprimé			C	Oral	5 Mg		Not Reported

Pelliculé Sécable

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654641	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030070		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029994			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Diclofenac	C	Oral	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654650	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030021		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654666	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1221569			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In	Azithromycine Dihydratee			S	Oral	500 Mg		Not Reported

Unapproved Indication; Psychomotor Hyperactivity	Plaquenil 200 Mg, Comprime Enrobe		S	Oral	600 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654748	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3357368-00		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatocellular Injury	Kaletra 200/50			S	Oral	2 Comp/12h		Not Reported
	Kaletra 200/50			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Ceftriaxona			S				Not Reported
	Hidroxicloroquina			S	Oral	200mg/12h		Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654834	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate Sodium			S	Unknown			Pfizer
	Celebrex			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Xeljanz			S	Unknown			Pfizer
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655309	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002613			Unknown	FRA

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

Dyspnoea; Fatigue; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	Unk		Concordia
	Triatec [Ramipril]	C				Not Reported
	Doliprane	C				Not Reported
	Levothyrox	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655685	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1219067		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral	600 Milligram Daily;		Actavis
	Ibuprofen			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	120 Milligram Daily;		Not Reported
	Apremilast			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Disorder; Ulcer	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Benadryl	C			Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C			Not Reported
	Febuxostat	C			Not Reported
	Folic Acid	C			Not Reported
	Gravol	C			Not Reported
	Mogadon	C	Oral		Not Reported
	Nitrazepam	C	Unknown		Not Reported
	Oxycodone	C			Not Reported
	Prednisone	C			Not Reported
	Uloric	C	Unknown	160 Milligram Daily;	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655811	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220302		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Amlodipine Besilate			S	Oral			Teva
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Asacol			S	Unknown	2400 Milligram Daily;		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone Acetate			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Acetate			C	Intra-articular			Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tylenol			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655893	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002355			Unknown	BRA

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

Drug Dependence	Hydroxychloroquine	S	Unknown	(Strength: 400mg 2x15 Cprrev		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656013	EXPEDITED (15-DAY)		OT	GR-PBT-000004		68 YR	Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Disease Progression; Drug Ineffective; Product Use In Unapproved Indication; Vasculitic Rash	Tacrolimus			S	Unknown			Panacea Biotec
	Tacrolimus			S	Unknown			Panacea Biotec
	Thiamazole			C	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Two Monthly Intravenous Pulses		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656614	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656633	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea	Hydroxychloroquine	Y		S	Oral	Quantity:10 Tablet(S);		Not Reported
	Breo			C				Not Reported
	Dupixent			C				Not Reported
	Green Tea			C				Not Reported
	Magnesium			C				Not Reported
	Black Seed Oil			C				Not Reported
	Blessed Thistle			C				Not Reported
	Sunflower Lecithin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657153	EXPEDITED (15-DAY)		OT	PL-AMNEAL PHARMACEUTICALS-2020-AMRX-01107		54 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2x/Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657180	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220398		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased;	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Gliclazide			S	Unknown			Not Reported

Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Enbrel	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Asacol Also Known As Mesalamine	S	Unknown	2400 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Diamicron	S	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait	Ramipril			S	Oral			Actavis

Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Ramipril		S	Unknown		Actavis
	Acetaminophen		S	Unknown		Not Reported
	Dorzolamide/Timolol		S	Unknown	2 Dosage Forms Daily;	Actavis
	Dorzolamide/Timolol		S	Unknown		Actavis
	Prednisone		S	Unknown		Actavis
	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Levothyroxine		S	Unknown		Not Reported
	Levothyroxine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	16079912	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Parenteral			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Parenteral		Not Reported
Methotrexate	S	Parenteral		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Oral	Unknown	Not Reported
Plaquenil	S	Oral	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Subcutaneous	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown, Solution	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Abatacept	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Subcutaneous	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
Leflunomide	S	Oral	Unknown	Not Reported
Actemra	C	Unknown	Unknown	Not Reported
Azathioprine	C	Unknown	Unknown	Not Reported
Ciclosporin	C	Unknown	Unknown	Not Reported
Minocycline	C	Unknown	Unknown	Not Reported
Penicillamine	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported
Tocilizumab	C	Unknown	Unknown	Not Reported
D-Penicillamine	C	Unknown	Unknown	Not Reported
Prednisolone	C	Unknown		Not Reported

	Cyclosporin		C	Unknown	Unknown	Not Reported
	Phenylbutazone		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658279	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01638		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658282	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01639		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658365	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2762682-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Metabolic Surgery; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Allopurinol			C				Not Reported

Pantoloc	C	Unknown		Not Reported
Zyloprim	C			Not Reported
Clomipramine	C	Unknown		Not Reported
Plaquenil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030120			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown	100 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milliliter, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	14778692	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009922			Female	CAN

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

Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Hydroxychloroquine	S	Oral	Unk		Apotex
	Leflunomide	S	Oral	Unk		Apotex
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Methotrexate	C	Unknown	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16140356	EXPEDITED (15-DAY)		OT	PHHY2019CA070200		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16408931	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA127221		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear	Voltaren			S	Unknown	Unk		Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Diclofenac Potassium			S	Unknown			Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac			S	Unknown	Unk		Novartis

Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac	S			Novartis
	Diclofenac	S			Novartis
	Diclofenac	S			Novartis
	Acetylsalicylic Acid Sandoz	S	Unknown	325 Mg	Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Vitamin C	S	Unknown		Not Reported
	Clopidogrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Motrin	S	Unknown		Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S			Not Reported

Plaquenil	S				Not Reported
Plaquenil	S				Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown			Not Reported
Aspirin	S	Oral	Unk		Not Reported
Aspirin	S				Not Reported
Aspirin	S				Not Reported
Aspirin	S				Not Reported
Naprosyn	S	Unknown			Not Reported
Naprosyn	S				Not Reported
Naprosyn	S				Not Reported
Naprosyn	S				Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown			Not Reported
Apo Sulfatrim	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Oral			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Sulphamethoxazole	S	Unknown			Not Reported
Apo-Diclofenac	S	Unknown			Not Reported
Sulfatrim	S	Unknown			Not Reported
Tramadol Hcl	C	Unknown			Not Reported
Tramadol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16762680	EXPEDITED (15-DAY)		OT	DE-DEXPHARM-20190689			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Quensyl			S	Unknown			Not Reported
	Eliquis			S		2.5 Mg Bid		Not Reported
	Roactemra			S				Not Reported
	Spasmolyt			S				Not Reported
	Spasmolyt			S				Not Reported
	Omeprazole			S	Oral	20 Mg Every 12 Hours: In		Not Reported

				The Morning And In The Evening	
	Ramipril	S	Oral	In The Morning And In The Evening	Not Reported
	Volibris	S			Not Reported
	Sildenafil Citrate	S			Not Reported
	Lyrica	S		100 Mg, Tid	Not Reported
	Pregabalin	S		1 Df, 3x/Day (1 - 1- 1)	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17271238	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000259			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Eye; Dry Mouth; Lower Respiratory Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Salagen			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D3			C		25 Ug		Not Reported
	Methotrexate			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Arthrotec			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Omega 3			C		Unk		Not Reported
	Orthotics			C				Not Reported
	Orthotics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17488060	NON-EXPEDITED			US-PFIZER INC-2020092938		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Disorder; Breast Cyst; Bronchitis; Chest Pain; Condition Aggravated; Dyspnoea; Fibromyalgia; Frustration Tolerance Decreased; Insomnia; Joint Swelling; Malaise; Memory Impairment; Musculoskeletal Stiffness; Nodule; Osteoarthritis; Pain; Product Dose Omission; Respiratory Disorder; Weight Increased	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17532940	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	520 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17658870	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001936			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659181	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002316			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Irbesartan			C		Unk		Not Reported
	Lercanidipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659505	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030160		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Prescribed Underdose	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported

Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Endocervical			Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030087		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qh		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Risedronate Sodium			S	Unknown	35 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported

	Simponi		S	Subcutaneous	Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660024	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145583		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Incorrect Route Of Product Administration; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Celebrex			S	Unknown			Pfizer
	Enbrel			S	Subcutaneous			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	500 Mg, Unk		Pfizer
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, 1 Every 1 Day		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Endocervical			Not Reported
	Risedronate Sodium			S	Unknown	5 Mg, Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg, Unk		Not Reported
	Desoximetasone			C	Unknown	5 Mg, 1x/Day		Not Reported
	Desoximetasone			C	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown	5 Mg,1 Every 1 Day		Not Reported
	Tylenol [Paracetamol]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660080	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Myochrysine			S	Unknown			Not Reported
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660089	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660093	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146051			Female	CAN

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

Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Methotrexate Sodium		S	Oral	Unk	Pfizer
	Methotrexate Sodium		S	Intravenous (not otherwise specified)	Unk	Pfizer
	Celebrex		S	Unknown	Unk	Pfizer
	Sulfasalazine		S	Unknown	Unk	Pfizer
	Rituximab		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Belimumab		S	Unknown	Unk	Not Reported
	Breo Ellipta		S	Respiratory (inhalation)	Unk	Not Reported
	Colchicine		S	Unknown		Not Reported
	Dexilant		S	Oral	60 Mg, 1x/Day	Not Reported
	Estrogel		S	Topical	Unk Unk, 1x/Day	Not Reported
	Meloxicam		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	200 Mg, 2x/Day	Not Reported
	Prednisone		S	Unknown	50 Mg, Unk	Not Reported
	Ventolin Hfa		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661320	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661328	DIRECT	Y	OT			51 YR	Female	USA

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

Transaminases Increased	Hydroxychloroquine		S	Oral	Not Reported
	Lopinavir/Ritonavir		S		Not Reported
	Atorvastatin 80mg		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661548	EXPEDITED (15-DAY)		OT	NVSC2020CA096823		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate Disodium			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate Disodium			S	Oral	20 Mg, Qw		Not Reported
	Ciclosporin Sandoz			S	Subcutaneous	Unk		Novartis
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q2w		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Unknown	75 Mg, Qmo		Not Reported

	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Avara	C	Oral	20 Mg, Qd	Not Reported
	Rituxan	C	Unknown	500 Mg, Qd	Not Reported
	Cimzia	C	Subcutaneous	200 Mg, Q2w	Not Reported
	Risedronate	C	Oral	25 Mg, Qw	Not Reported
	Risedronate	C	Oral	30 Mg, Qw	Not Reported
	Plaquenil	C	Oral	200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661837	EXPEDITED (15-DAY)		OT	NVSC2020CA097860		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin Sandoz			S	Unknown			Novartis

	Sulfasalazine	S	Oral		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661903	DIRECT	Y	LT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Plaquenil			S				Not Reported
	Azithromycin Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662053	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1223033		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral	Unknown Dosage		Not Reported
	Plaquenil			S	Oral	800 Mg		Not Reported
	Augmentin			C	Oral	Unknown Dosage		Not Reported
	Hypnovel			C				Not Reported
	Sufentanil			C				Not Reported
	Etomidate			C				Not Reported
	Tracrium			C				Not Reported
	Esmeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662107	EXPEDITED (15-DAY)		OT	NVSC2020CA097244		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral	5 Mg, Qd (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662227	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002617			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus; Stress	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662417	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003003386			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Zinc Salt Nos			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662684	EXPEDITED (15-DAY)		OT	NVSC2020US098481			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	(1.2-8.3) Mg/Kg		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662798	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1222453		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663000	EXPEDITED (15-DAY)		OT	NVSC2020CA098112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dactylitis; Drug	Cosentyx			S	Unknown	300 Mg, Qmo		Novartis

Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Azathioprine	S	Unknown		Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663200	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003002813			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663224	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002823			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Nivaquine			S	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663282	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002844			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Fall; Femur Fracture; Hypoacusis; Intentional Product Use Issue; Product Dose Omission; Unevaluable Event	Hydroxychloroquine			S	Unknown	2cp/Day, Qd		Concordia
	Hydroxychloroquine			S		1cp/Day For 15		Concordia
	Cardensiel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663302	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002921			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663508	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3361937-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663522	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362044-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663539	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362011-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665337	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine Oral Tablet			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665521	DIRECT	Y	DE, HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine 200mg Po			S	Oral			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14144042	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020346		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported

Anakinra	S	Subcutaneous	100 Mg, Unk		Not Reported
Anakinra	S	Subcutaneous	100 Mg, Qd		Not Reported
Anakinra	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Once Every Four Weeks		Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk 1 Every 4 Months		Not Reported
Orencia	S	Unknown	500 Unk, Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported
Xeljanz	C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14243063	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex

Systemic Lupus Erythematosus	Winpred	S	Oral	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14404773	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005233			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Reactine /00884302/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14558788	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262991-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15132896	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014806			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus	Pantoprazole			S	Transplacental	40 Milligram, Qd, 40 [Mg/D]; 0-13.6 Gestational Week		Macleods
	Pantoprazole			S	Transplacental	Unk		Macleods
	Aspirin			S	Transplacental	100 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	10 Milligram, Bid, Tablet,		Not Reported

Persistent; Ventricular Septal Defect				From Gestational Week 0-14	
	Simvastatin	S	Transplacental	Unk	Not Reported
	Simvastatin	S	Transplacental	Unk, Tablet, From Gestational Week 0-14	Not Reported
	Tacrolimus	S	Transplacental	6 Milligram, Qd, From Gestational Week 0-14	Not Reported
	Tacrolimus	S	Transplacental	Unk, 1 Trimester	Not Reported
	Tacrolimus	S	Transplacental	Unk	Not Reported
	Heparins, Low-Molecular-Mass	S	Transplacental	Unk	Not Reported
	Heparins, Low-Molecular-Mass	S	Transplacental	Unk	Not Reported
	Salbutamol Sulfate	S	Transplacental	Unk Unk, Qd, From Gestational Week 0-14	Not Reported
	Salbutamol Sulfate	S	Transplacental	Unk	Not Reported
	Metamizole Sodium	S	Transplacental	Unk	Not Reported
	Metamizole Sodium	S	Transplacental	Unk,From Gestational Week 0-14	Not Reported
	Nicotine	S	Transplacental	Unk	Not Reported
	Nicotine	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported
	Ramipril	S	Transplacental	20 Milligram, From Gestational Week 0-13+6 Weeks) Maternal Dose 20 Mg	Not Reported
	Hydroxychloroquine	S	Transplacental	400 Milligram, Qd, From Gestational Week 0-14	Not Reported
	Aliskiren	S	Transplacental	300 Milligram, Qd, 300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
	Aliskiren	S	Transplacental	Unk	Not Reported
	Rivaroxaban	S	Transplacental	Unk	Not Reported
	Rivaroxaban	S	Transplacental	Unk	Not Reported
	Ezetimibe	S	Transplacental	Unk, Tablet, From	Not Reported

			Gestational Week 0-14	
Ezetimibe	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	100 Mg Qd From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	Unk, Film Coated Tablet,From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd, 2 X 100	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional, Trimester: Preconceptional	Not Reported
Rasilez	S	Unknown		Not Reported
Enoxaparin Sodium	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd	Not Reported
Novaminsulfon	S	Transplacental	Unk, Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	Unk, 3000 [Mg Cumulative]; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15622524	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557260-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Diclofenac	C		Not Reported
	Desoximetasone	C	Oral	Not Reported
	Xeljanz	C	Subcutaneous	Not Reported
	Zostavax	C	Subcutaneous	Not Reported
	Methotrexate	C		Not Reported
	Voltaren	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15806693	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2618205-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Parenteral	Foa-Solution Inramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not	Foa-Solution Intravenous	Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Alendronate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Etanercept	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Codeine Sulfate	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16079861	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06082		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment	Etanercept	S	Subcutaneous	Unknown	Not Reported
	Etanercept	S	Unknown	Unknown	Not Reported
	Etanercept	S			Not Reported
	Apo-Ibuprofen	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral	Unknown	Not Reported
	Apremilast	S	Oral		Not Reported
	Apremilast	S	Unknown	Unknown	Not Reported
	Apremilast	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Ciclosporin	S	Subcutaneous	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown (Solution), Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unknown (Solution)	Not Reported
	Golimumab	S	Subcutaneous	Unknown	Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Unknown		Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Otezla	S	Oral		Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Otezla	S			Not Reported
	Simponi	S	Subcutaneous	Unknown (Solution)	Not Reported
	Stelara	S	Subcutaneous	Unknown (Solution)	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Ustekinumab	S	Subcutaneous	Unknown	Not Reported

Failure; Ulcer	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Sulfamethoxazole	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Colchicine	C	Oral		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Oral	Unknown	Not Reported
	Methotrexate	C	Unknown	Unknown	Not Reported
	Mogadon	C	Unknown		Not Reported
	Nitrazepam	C	Oral		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Oxyneo	C	Unknown	(Extended Release)	Not Reported
	Uloric	C	Oral		Not Reported
	Benadryl	C	Unknown	Unknown	Not Reported

	Dexilant	C	Unknown	Unknown (Delayed Release)	Not Reported
	Dexilant	C	Unknown	Unknown, Prolonged Release	Not Reported
	Gravol	C	Unknown	Unknown	Not Reported
	Oxycodone	C	Unknown		Not Reported
	Oxycodone	C	Unknown		Not Reported
	Acide Folique	C	Unknown	Unknown	Not Reported
	Methotrexate Sodium	C	Oral		Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16589246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2851920-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16954774	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972637-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Humira			S	Subcutaneous			Not Reported
	Plantago Afra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Cannabis Sativa			C				Not Reported
	Tums			C				Not Reported
	Lipitor			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Calcium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17543919	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA072124		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported

Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unknown	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unknown	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	5 Mg, Bid	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Mg, Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Endocervical	400 Mg	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported

	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Insulin	C	Oral	Unk (Drops)	Not Reported
	Metformin	C	Unknown	2 Df, Bid	Not Reported
	Metformin	C	Unknown	1 Unk	Not Reported
	Plaquenil	C	Unknown		Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17552068	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2020JPN044468		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection	Belimumab			S	Intravenous drip	Unk		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks		Glaxosmithkline
	Prednisolone			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	10 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	9 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	8 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	7 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	6 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	7 Mg, 1d		Glaxosmithkline

	Prednisolone	S	Oral	8 Mg, 1d	Glaxosmithkline
	Tacrolimus	S	Unknown	Unk	Glaxosmithkline
	Imuran	S	Unknown	Unk	Glaxosmithkline
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Bonoteo	C		Unk	Not Reported
	Lansoprazole	C		Unk	Not Reported
	Bayaspirin	C		Unk	Not Reported
	Rebamipide	C		Unk	Not Reported
	Baktar	C		Unk	Not Reported
	Colonel	C		Unk	Not Reported
	Loxofen (Loxoprofen Sodium)	C		Unk	Not Reported
	Amerge	C		Unk	Not Reported
	Sumilu Stick	C		Unk	Not Reported
	Celecox	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17636246	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000165			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Rivaroxaban			S	Transplacental			Not Reported
	Rivaroxaban			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported

	Pantoprazole	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Ezetimibe	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663632	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018207		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day (Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day (1gr Cada 8 Horas)		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day (Dia)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day (Dia)		Not Reported
	Dolquine			S				Not Reported
	Simvastatina Alter			S	Oral	0-0-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147529		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Mg, Monthly		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663950	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021948		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apremilast			S	Unknown	30 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	30 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Otezla		S	Unknown	30 Mg, Bid	Not Reported
	Prednisone		C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664171	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1698			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664175	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664213	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3361763-00		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Kaletra 200/50			S	Oral			Not Reported
	Quetiapina			S	Oral			Not Reported
	Levofloxacino			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Risperidona			S	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamicina Hidrocloruro			C	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemida			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664281	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664285	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664555	EXPEDITED (15-DAY)		OT	HK-ACCORD-178663		67 YR	Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis	Methotrexate			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665668	NON-EXPEDITED		HO, OT	NVSC2020US099010		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Hepatitis Viral; Nausea; Pyrexia	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665946	EXPEDITED (15-DAY)		DE, HO, OT	SK-HORIZON-PRE-0109-2020		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cyclosporine A			S				Not Reported
	Methotrexate			S				Not Reported
	Belimumab			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17666426	EXPEDITED (15-DAY)		OT	NVSC2020PT099374		48 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667548	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2375555-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

Product Effect Decreased; Therapeutic Product Effect Decreased	Leucovorin Calcium	C	Not Reported
	Codeine	C	Not Reported
	Ibuprofen	C	Not Reported
	Dilaudid	C	Not Reported
	Plaquenil	C	Not Reported
	Acetaminophen	C	Not Reported
	Ventolin Hfa	C	Not Reported
	Nexium Dr	C	Not Reported
	Advair Diskus	C	Not Reported
	Allopurinol	C	Not Reported
	Cyclobenzaprine Hcl	C	Not Reported
	Atrovent Hfa	C	Not Reported
	Hydromorphone Hcl	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667856	EXPEDITED (15-DAY)		OT	NVSC2020CA098863		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668265	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017705			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

Unapproved Indication;
Psychomotor Hyperactivity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3362555-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668434	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030217		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2 Weeks, Duration 1 Days And 15 Days		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks, Duration 2.0 Years		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
	Leflunomide	S	Oral	10 Milligram, Duration 2 Months	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Week, Duration 2 Months	Not Reported
	Plaquenil S	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	5 Milligram, 2 Every 1 Days	Not Reported
	Viread	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668438	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-017975		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Product Use In Unapproved Indication	Clindamycin			S	Unknown	300 Milligram, Two Times A Day		Aurobindo
	Rifampin			S	Unknown	600 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day (Monday Through		Not Reported

	Clobetasol	S	Unknown	Friday) Unk Unk, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17669671	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Anxiety; Burning Sensation; Fatigue; Muscle Spasms; Nervous System Disorder; Nonspecific Reaction; Pain Of Skin; Pruritus	Hydroxychloroquine Sulfate Plaquenil			S	Oral	Quantity:1 Tablet(S);	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	8792714	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-009507513-1209DEU004039			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Simvastatin			S	Transplacental	Unk		Merck
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Merck
	Viemm 10 Mg Tabletten			S	Transplacental	From Gestational Week 0-14		Merck
	Aspirin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Enoxaparin Sodium			S	Transplacental	From Gestational Week 0-14		Not Reported
	Albuterol			S	Transplacental	From Gestational Week 0-14		Not Reported

Torsemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Dipyrone	S	Transplacental	From Gestational Week 0-14	Not Reported
Ramipril	S	Transplacental	20 Mg Unk From Gestational Week 0-113+6	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Heparin	S	Transplacental	Unk	Not Reported
Clexane (Enoxaparin Sodium)	S	Transplacental	200 Mg/D (2x100)	Not Reported
Hydroxychloroquine Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	14235439	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15391128	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-955090		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral			Actavis
	Perindopril			S	Oral			Not Reported
	Perindopril			S	Unknown			Not Reported
	Plaquenil			S	Oral	200 Mg/ Day		Not Reported
	Cortancyl			S	Oral	20 Milligram Daily; 10-20µg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15625329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558387-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported

Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Duration:365.0	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Prednisone	C	Endocervical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15760613	NON-EXPEDITED			US-PFIZER INC-2018522861		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Heparin Sodium			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Duloxetine			S	Oral	100 Mg, Daily		Not Reported
	Insulin			C		Unk		Not Reported
	Januvia			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Losartan/Hctz			C		Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15819449	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-DRREDDYS-GER/GER/19/0106738			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg Unk From Gestational Week 0-113+6		Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Not Reported
	Salbutamol			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5 082(Film Coated Tablet)		Not Reported
	Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Not Reported
	Dalteparin Sodium			S	Transplacental			Not Reported
	Heparin (Salt Not Specified)			S	Transplacental	Unk Unk,Unk		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Enoxaparin Sodium			S	Transplacental	200 Mg/D (2x100)		Not Reported
	Rituximab			S	Transplacental	Last Time In December 2011: Pre Or Periconceptional		Not Reported

Clexane	S	Transplacental	200 Mg/D (2x100)		Not Reported
Heparin Lmw	S	Transplacental	Unk		Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14		Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14		Not Reported
Prednisolone	S	Transplacental	From Gestational Week 0-14		Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5		Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional		Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17182091	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019231676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline

Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
Cimzia (Certolizumab Pegol)	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram Solution	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Solution	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine)	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17422218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04558		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celecoxib			S	Unknown	Unknown		Not Reported
	Celecoxib			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported

Prednisone	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown	Unknown	Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Cipralex (Escitalopram)	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Gabapentin	C	Unknown		Not Reported

Gabapentin	C	Oral			Not Reported
Hydrochlorothiazide	C	Unknown			Not Reported
Hydromorphone Hydrochloride	C	Oral			Not Reported
Hydromorphone Hydrochloride	C	Oral			Not Reported
Mupirocin	C	Topical	Unknown		Not Reported
Pantoloc (Pantoprazole)	C	Unknown			Not Reported
Shark Liver Oil	C	Unknown	Unknown		Not Reported
Tapentadol Hydrochloride	C	Unknown			Not Reported
Taro-Mupirocin	C	Topical	Unknown		Not Reported
Tramadol Hydrochloride	C	Oral			Not Reported
Tramadol Hydrochloride	C				Not Reported
Tramacet	C	Oral			Not Reported
Tramacet	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17643631	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-015943			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Drug Reaction With Eosinophilia And Systemic Symptoms; Pemphigus; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Aciclovir			S	Unknown	Unk		Aurobindo
	Cefixime			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Fluconazole			S	Unknown	Unk		Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Paracetamol			S	Unknown	Unk		Aurobindo
	Risperidone			S		Unk		Aurobindo
	Terbinafine			S	Unknown	Unk		Aurobindo

Ampicillin;Sulbactam	S	Unknown	Unk	Not Reported
Ketoprofen	S	Unknown	Unk	Not Reported
Clarithromycin	S	Unknown	Unk	Not Reported
Aspirin	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Vancomycin	S	Unknown	Unk	Not Reported
Enoxaparin	S	Unknown	Unk	Not Reported
Ceftazidime	S	Unknown	Unk	Not Reported
Oxacillin	S	Unknown	Unk	Not Reported
Clindamycin	S	Unknown	Unk	Not Reported
Carbamazepine	S	Unknown	Unk	Not Reported
Phenytoin	S	Unknown	Unk	Not Reported
Phenobarbital	S	Unknown	Unk	Not Reported
Teicoplanin	S	Unknown	Unk	Not Reported
Rufinamide	S	Unknown	Unk	Not Reported
Cotrimoxazole	S	Unknown	Unk	Not Reported
Cisplatin	S	Unknown	Unk	Not Reported
Fluorouracil	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Lithium	S	Unknown	Unk	Not Reported
Methylphenidate	S	Unknown	Unk	Not Reported
Acetylcysteine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17648818	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020061361		43 YR	Female	ITA

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

Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Belimumab		S	Unknown	Unk	Glaxosmithkline
	Belimumab		S	Unknown	Unk	Glaxosmithkline
	Belimumab		S	Unknown	Unk	Glaxosmithkline
	Tacrolimus		S	Unknown	Unk Unk, Qd	Glaxosmithkline
	Prednisone		S	Unknown	25 Mg, Qd	Not Reported
	Prednisone		S	Unknown	12.5 Mg, Qd	Not Reported
	Prednisone		S	Unknown	15 Mg, Qd	Not Reported
	Prednisone		S	Unknown	15 Mg, Qd	Not Reported
	Prednisone		S	Unknown	7.5 Mg, Qd	Not Reported
	Prednisone		S	Unknown	10 Mg, Qd	Not Reported
	Prednisone		S	Unknown	50 Mg, Qd	Not Reported
	Prednisone		S	Unknown	25 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate		S		400 Mg, Qd	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk, Qd	Not Reported
	Rituximab		C	Unknown	Unk	Not Reported
	Methylprednisolone		C	Unknown	Unk (Pulses)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668607	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030971		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Desoximetasone	C	Unknown	10 Milligram, Qd	Not Reported
	Diclofenac	C	Unknown	100 Milligram, Qd	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Voltaren [Diclofenac Sodium]	C	Unknown	100 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zostavax	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668861	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1720		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

	Prednisolone	S	Unknown	Not Reported
	Prednisone	S	Endocervical	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone Acetate	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1721		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668886	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1730			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Musculoskeletal Stiffness; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Aralen Hydrochloride			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669462	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669590	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C		20 Mg, Qd		Not Reported
	Tylenol Arthritis Pain			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Arava			S	Oral			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1.0 Df, Qw		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	40 Mg, Qw		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669592	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Injury	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Humira			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669596	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA096531		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Arava			S	Oral	20 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669689	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2020M1037212		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Acetaminophen			C	Unknown	6 Gram		Mylan
	Metronidazole			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669899	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009850			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk	Leflunomide			S	Transmammary	Unk		Apotex
	Hydroxychloroquine			S	Transmammary	Unk		Apotex
	Methotrexate			S	Transmammary	Unk		Not Reported
	Enbrel			S	Transmammary	Unk		Not Reported
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported
	Prednisone			C	Transmammary	Unk		Not Reported
	Sulfasalazine			C	Transmammary	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669916	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Torsade De Pointes	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S			1 DAY	Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S			2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670426	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-2020-NL-1222817		31 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva

	Certolizumab Pegol		S	Subcutaneous	200 Mg, Q2w	Not Reported
	Omeprazole		C	Oral	20 Milligram Daily;	Not Reported
	Novorapid		C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670440	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1223401		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Levofloxacino (2791a)			S	Unknown			Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Lopinavir+Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Ceftriaxona (501a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671067	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Plaquenil			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671115	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Prednisone			S		1 Df, Qw		Not Reported
	Prevacid			C				Not Reported
	Risedronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671152	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223013		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Hidroxicloroquina (2143a)			S	Oral	2-5 Day: 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral	1 Day: 400mg / 12h, 2-5 Day: 200mg / 12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223386		68 YR	Male	ESP

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

Hepatitis	Hidroxicloroquina (2143a)	S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)	S				Teva
	Azitromicina (7019a)	S	Oral	500 Milligram Daily; 500mg/24h		Not Reported
	Azitromicina (7019a)	S				Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671318	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

Width Decreased;
Rheumatoid Arthritis;
Vascular Access
Complication; White Blood
Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672057	NON-EXPEDITED			US-CELGENEUS-USA-20200403202		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672078	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1221322			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Flutter	Hydroxychloroquine Sulfate Watson			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672447	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-12513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

Methotrexate	S	Unknown	Unknown		Not Reported
Orencia	S	Unknown	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown		Not Reported
Tocilizumab	S	Unknown	Unknown		Not Reported
Azathioprine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672893	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3363203-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Lipitor			S	Oral			Not Reported
	Dovobet			C	Topical			Not Reported
	Folic Acid			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Flovent			C	Respiratory (inhalation)			Not Reported
	Ventolin			C	Respiratory (inhalation)			Not Reported
	Vitamin D2			C	Oral			Not Reported

	Multi Vitamin		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pneumococcal Vaccine Polysacch 23v			C	Unknown			Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Varicella Zoster Vaccine Live			C	Unknown			Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030963		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Orencia			S	Endocervical			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673612	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673774	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004002881			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Malaise; Systemic Lupus Erythematosus Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673830	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002619			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Inflammation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674032	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018904		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported

	Ceftriaxone		C	Intravenous (not otherwise specified)	1 Gram, Once A Day	Not Reported
	Tocilizumab		C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674037	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018903		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674055	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018905		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Dolquine			S	Other	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674074	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid	Orencia			S	Endocervical			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported

Arthritis; Stress	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mefenamic Acid	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Prednisone	C	Oral	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674075	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018907		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Azithromycin			S	Oral	500 Milligram, Once A Day		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17675095	DIRECT	Y	DE			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Pulmonary Embolism; Unresponsive	Hydroxychloroquine			S	Oral			Not Reported

To Stimuli

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	14409544	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP005298		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Voltaren /00372301/			S	Unknown	Unk		Not Reported
	Sulfamethoxazole W/Trimethoprim			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Tramadol Hcl			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	14933830	EXPEDITED (15-DAY)		DS, OT	GB-SA-2018SA139931		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio	Leflunomide			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S				Sanofi
	Erythromycin			S				Sanofi
	Arava			S				Sanofi
	Demerol			S				Sanofi

Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol Fumarate	S	Unknown	Tablet	Not Reported
	Methotrexate	S	Oral	1 Df, Qw	Not Reported
	Metronidazole	S			Sanofi
	Norfloxacin	S			Not Reported
	Cefaclor	S			Not Reported
	Erythromycin	S			Sanofi
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Pregabalin	S			Not Reported
	Sulfasalazine	S			Not Reported
	Prednisone	S	Unknown		Not Reported
	Erythromycin Estolate	S		Unk	Not Reported
	Levofloxacin	S			Not Reported
	Arthrotec	S			Not Reported
	Meperidine Hydrochloride	S			Not Reported
	Plaquenil	S			Sanofi
	Norfloxacin	S		400 Mg	Not Reported
	Celecoxib	S	Oral	200 Mg	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Prednisone	S			Not Reported
	Bisoprolol Fumarate	S			Not Reported
	Bisoprolol Salt Not Specified	S			Not Reported
	Humira	S	Subcutaneous	400 Mg	Not Reported
	Diclofenac Sodium/Misoprostol	S			Not Reported
	Methotrexate Sodium	S			Not Reported
	Pethidine Hydrochloride	S			Sanofi
	Sulfasalazine	S		500 Mg	Not Reported
	Levofloxacin Hemihydrate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16205860	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039198		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity;	Metformin Hydrochloride			S	Unknown	1000 Milligram Daily;		Actavis
	Desoximetasone			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Altace	C	Unknown	5 Milligram Daily;	Not Reported
	Asa	C	Unknown	81 Milligram Daily;	Not Reported
	D-Alpha Tocopherol/Fish Oil	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Oral	15 Milligram Daily;	Not Reported
	Rosuvastatin Calcium	C	Unknown	20 Milligram Daily;	Not Reported
	Vitamin D /00107901/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16582688	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2852957-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Indocid			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16844994	EXPEDITED (15-DAY)		OT	GR-PFIZER INC-2019378939		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S		Unk		Pfizer
	Lansoprazole			S	Unknown	Unk		Pfizer
	Ramipril			S	Unknown	Unk		Pfizer
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Thyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Metformin Hydrochloride			S		Unk		Not Reported
	Levothyroxine Sodium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17302274	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA014510		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect	Leflunomide			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi

Incomplete; Vomiting	Methotrexate	S	Oral	Unk Unk, Qw	Not Reported
	Metronidazole	S	Unknown	Unk	Sanofi
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Demerol	S	Unknown	Unk	Sanofi
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	400 Mg	Not Reported
	Bisoprolol Salt Not Specified	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Erythromycin	S	Unknown	Unk	Sanofi
	Erythromycin	S	Unknown	Unk	Sanofi
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Sanofi
	Plaquenil	S	Oral	Unk	Sanofi
	Arthrotec	S	Unknown	Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17315972	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20.0 Mg, Qd (20.0 Milligram 1 Every 1 Days)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1 Days)		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg (Every 2 Weeks)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Once Every 2 Weeks)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17365657	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine			S				Sanofi

Leflunomide	S	Oral			Sanofi
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S				Not Reported
Methotrexate	S				Not Reported
Arava	S				Sanofi
Prednisone	S				Not Reported
Sulfasalazine	S		500 Mg		Not Reported
Actemra	S				Not Reported
Cimzia	S	Subcutaneous			Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Subcutaneous			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Simponi	S	Subcutaneous			Not Reported
Desoximetasone	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17486747	EXPEDITED (15-DAY)		OT	IT-VELOXIS PHARMACEUTICALS-2020VELIT-000200		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Off Label Use	Envarsus			S	Unknown	Unk, Qd		Chiesi
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg Qd, Tapering Dose		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported

	Prednisone	S	Unknown	15 Mg Qd, Dose Tapering	Not Reported
	Prednisone	S	Unknown	10 Mg Qd, Dose Tapering	Not Reported
	Prednisone	S	Unknown	7.5 Mg Qd, Dose Tapering	Not Reported
	Prednisone	S	Unknown	12.5 Mg Qd, Dose Tapering	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Immunoglobulin I.V	C		Unk	Not Reported
	Rituximab	C		Unk	Not Reported
	Methylprednisolone	C		Unk (Pulses)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17511082	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200240044			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605625	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333276		41 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605640	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333287		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17670489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1222995		71 YR	Male	ESP

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

Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Hydroxychloroquine		S	Oral	400 Milligram Daily; 200 Mg/12h	Teva
	Kaletra		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673141	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673245	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018502		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Propofol			S	Intravenous (not otherwise specified)	6.6 Milligram/Kilogram, 1 In Hour, (Sedation)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

	Dexamethasone	C	Intravenous (not otherwise specified)	4 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674049	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001167			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Dyspnoea Exertional	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674369	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096501			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Hydroxychloroquine			S				Sanofi
	Colchicine			S				Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Methylprednisolone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S		150 Mg, Qd		Not Reported
	Bromocriptin Ct			S				Not Reported
	Ciclosporin			S				Not Reported
	Dilaudid			S				Not Reported
	Doxycycline Hyclate			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S				Not Reported
	Humira			S		40 Mg		Not Reported
	Mercaptopurin			S				Not Reported
	Pamidronate Disodium			S				Not Reported
	Tenoxicam			S				Not Reported
	Ustekinumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674370	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097034			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674433	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020154341		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Tacrolimus Monohydrate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Pentasa			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674454	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365014-00		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Azitromicina			S	Oral			Not Reported
	Azitromicina			S				Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674455	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3365006-00		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Ceftriaxona			S				Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674480	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365040-00		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Interferon Beta-1b			S				Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674601	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout; Hypertension; Palpitations	Metformin			S	Unknown			Actavis
	Sumatriptan Succinate			S	Unknown			Teva
	Colchicine			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674602	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1222322		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Metformin			S	Unknown	1000 Milligram Daily;		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Furosemide			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium Bromide/Salbutamol Sulfide			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec [Omeprazole]			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol[Paracetamol]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674609	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-243893		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Prednisolone			S	Unknown	20 Milligram, Unk		Taro
	Prednisolone			S	Unknown	40 Milligram, Daily		Taro
	Sulfasalazine			S	Unknown	Unk		Sun
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674739	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222306		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Metformin Hydrochloride			S	Unknown			Actavis
	Metformin Hydrochloride			S				Actavis
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xarelto			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674823	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1741		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Leflunomide	S	Unknown	Not Reported
Calcium/Vitamin D3	C	Unknown	Not Reported
Hydrocortisone	C	Unknown	Not Reported
Pantoloc	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xarelto	C	Unknown	Not Reported
Tylenol Arthritis Pain	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674993	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1036998		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma Skin; Mycobacterium Marinum Infection	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Mylan
	Prednisolone			S	Unknown	Low-Dose		Mylan
	Prednisolone			S	Unknown	20 Milligram(Dose Was Increased To 40mg Daily)		Mylan
	Sulfasalazine			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan
	Metoprolol			C	Unknown			Mylan
	Amlodipine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675138	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Codeine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Sulfate]					
Arava	C	Unknown	20 Mg, 1x/Day		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675164	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2607481-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pms Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675304	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-010799			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Graft Versus Host Disease In Skin	Prednisolone			S	Unknown			Bausch And Lomb
	Ciclosporin			S	Unknown			Not Reported
	Ibrutinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Sirolimus	S	Unknown		Not Reported
	Bactrim Ds	C			Not Reported
	Quetiapine	C			Not Reported
	Valaciclovir	C			Not Reported
	Lamotrigine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675370	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223716		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h,		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Comp/12h, 2 Dosage Forms		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675600	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096344		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical	Plaquenil			S				Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Sulfasalazine			S		1 G		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Certolizumab Pegol			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Hydroxyquinoline Sulfate	S				Not Reported
	Neoral	S				Not Reported
	Rapamune	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus	S	Oral	2 Mg, Q12h		Not Reported
	Tacrolimus	S	Oral	3 Mg, Q12h		Not Reported
	Imuran [Azathioprine]	C		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675748	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096669		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675975	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097036		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Adalimumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676292	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096405		57 YR	Male	CAN

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

Arthralgia; Arthropod Sting; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Hydroxychloroquine		S				Sanofi
	Leflunomide		S				Sanofi
	Methotrexate		S				Not Reported
	Codeine		S				Not Reported
	Humira		S	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676418	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Hydroxychloroquine			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Kaletra 200/50			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676757	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676812	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1224309		45 YR	Female	FRA

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

Agranulocytosis	Azithromycine Anhydre	S	Oral	500 Mg		Not Reported
	Plaquenil	S	Oral	600 Mg		Not Reported
	Ceftriaxone Base	C	Unknown			Not Reported
	Inipomp	C	Unknown			Not Reported
	Rovamycine	C	Unknown			Not Reported
	Paracetamol	C	Unknown			Not Reported
	Xarelto 10 Mg, Comprimé Pelliculé	C	Oral			Not Reported
	Diffu K	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677150	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097010		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cellulitis; Musculoskeletal Discomfort	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677153	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043120		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen			S				Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi

Methotrexate Sodium	S				Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Actemra	S	Unknown	Unk Unk,Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Unknown	1 Df, Qm		Not Reported
Rituximab	S				Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Risedronate	C	Oral	35 Mg, Qw		Not Reported
Arava	C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677300	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016052		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	25 Milligram, Weekly (Qw)		Not Reported
	Naproxen			C				Not Reported
	Hydroxyzine			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677732	EXPEDITED (15-DAY)		HO	SE-BAUSCH-BL-2020-011319		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Pcs		Not Reported
	Sertraline			S	Oral			Not Reported
	Plaquenil			S	Oral	10-15 Pcs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677745	EXPEDITED (15-DAY)		DS, HO, OT	US-ADVANZ PHARMA-			Unknown	USA

202004002453

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Occlusion	Hydroxychloroquine			S				Concordia
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677821	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018906		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo
	Risperidone			S	Oral	1 Milligram, Once A Day		Aurobindo
	Quetiapine			S	Oral	25 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Clindamycin Hydrochloride			C	Intravenous (not otherwise specified)	600 Milligram, Four Times/Day		Not Reported
	Losartan			C	Oral	50 Milligram, Once A Day		Not Reported
	Lorazepam			C	Oral	1 Milligram, Once A Day		Not Reported
	Furosemide			C	Oral	40 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17679795	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	18246716	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral		4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	18247364	DIRECT		HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection	Azithromycin			S	Oral	Other Dose:500mg/250mg;	4 DAY	Not Reported
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Other Dose:400 Bid The First Day Then 200mg Bid The Next 4 Days Iv	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	13473732	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S				Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex

Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Reactine /00884302/	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S			Not Reported
	Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
	Methotrexate	S			Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Plaquenil /00072602/	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not	Unk	Not Reported

					otherwise specified)					
	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15020708	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0100319		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To Various Agents	Docetaxel			S	Unknown	21-Day Cycles		Not Reported
	Anastrozole			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15839308	EXPEDITED (15-DAY)		CA, HO, OT	DE-JNJFOC-20190118228			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy; Hospitalisation; Premature Baby; Small For Dates Baby	Infliximab, Recombinant			S	Transplacental			Janssen
	Etanercept			S	Transplacental			Not Reported
	Adalimumab			S	Transplacental			Not Reported
	Certolizumab			S	Transplacental			Not Reported
	Anakinra			S	Transplacental			Not Reported
	Methotrexate			S	Transplacental			Not Reported
	Leflunomide			S	Transplacental			Not Reported
	Abatacept			S	Transplacental			Not Reported
	Tocilizumab			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported
	Ciclosporin			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15839309	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190118229			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Complication Of Pregnancy; Ectopic Pregnancy; Foetal Death; Gestational Diabetes; Gestational Hypertension; Haemorrhage; Hip Arthroplasty; Paternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16651301	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qw		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg, Qw Solution		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Actemra			S		Unk		Not Reported

	Enbrel	S		25 Mg, Qow	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S		125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Q6w	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17114842	EXPEDITED (15-DAY)		OT	DE-TORRENT-00015319			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Unknown
	Apixaban			S		2.5 Milligram, Bid		Unknown
	Eliquis			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Lyrica			S	Unknown	100 Milligram, Tid Capsule, Hard		Unknown
	Omeprazole			S	Oral	1 Df,2x/Day (1-0 -1)		Not Reported
	Pregabalin			S	Unknown	1 Df, Tid, 3x/Day (11-1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Ramipril			S	Oral	1 Df, Bid, 2x/Day (1-0-1)		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw Pre-Filled Syringe		Unknown

Sildenafil	S	Unknown	60 Milligram, Daily Dose		Not Reported
Spasmolyt	S	Unknown	1 Df, 15 (Unit Unspecified), Qd (1-0-0)		Unknown
Volibris	S	Oral	30 Milligram, Qd		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17386415	EXPEDITED (15-DAY)		OT	GR-EMD SERONO-E2B_90074536		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Metformin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Dicumarol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17402570	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17403255	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016019500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		5 Milligram Solution		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Orencia			S		750 Milligram		Not Reported

	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Prednisone	C		50 Milligram, Once Daily (Qd)	Not Reported
	Isoniazid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17411075	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-03838		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Gold			S	Intramuscular	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Oral			Not Reported

Azathioprine	S	Unknown	Unknown		Not Reported
Anakinra	S	Subcutaneous			Not Reported
Apo-Leflunomide	S	Unknown	Unknown		Not Reported
Azathioprine Sodium	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Leflunomide	S	Unknown	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)	Unknown		Not Reported
Docusate Sodium	C	Oral			Not Reported
Elavil	C	Unknown	Unknown		Not Reported
Prednisone	C	Oral			Not Reported
Sulfasalazine	C	Oral			Not Reported
Sulfasalazine	C	Unknown	Unknown		Not Reported
Tobramycin	C	Unknown			Not Reported
Doxycycline	C	Oral	Unknown		Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Elavil	C	Unknown	Unknown		Not Reported
Wellbutrin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17535019	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1196886		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Steatosis	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17583365	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17623465	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

Prednisolone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17628959	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202003002234			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hallucination; Headache; Nausea	Hydroxychloroquine			S	Unknown	1 Peice Daily, Film Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17656152	EXPEDITED (15-DAY)		CA, OT	FR-SA-2020SA091764			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Increased; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Lovenox			S	Transplacental	1 Df, Qd		Sanofi
	Lovenox			S	Transplacental	Unk		Sanofi
	Plaquenil			S	Transplacental	400 Mg, Qd		Sanofi
	Plaquenil			S	Transplacental	Unk		Sanofi
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	1 Df, Qd		Not Reported
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	Unk		Not Reported
	Econazole Nitrate			S	Transplacental	300 Mg, Qd		Not Reported
	Cortancyl			S	Transplacental	1 Df, Qd		Not Reported
	Cortancyl			S	Transplacental	Unk		Not Reported
	Imurel [Azathioprine]			S	Transplacental	150 Mg, Qd		Not Reported
	Imurel [Azathioprine]			S	Transplacental	Unk		Not Reported
	Econazole			C	Transplacental	300 Mg, Qd		Not Reported
	Econazole			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030940		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk Unk, Qd		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Minocycline			C	Unknown	Unk		Not Reported
	Penicillamine			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	6 Milligram, Bid		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016060			Female	CAN

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

Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia		S	Subcutaneous	Solution	Not Reported
	Actemra		S			Not Reported
	Arava		S	Oral	20 Milligram	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate		S	Oral	20 Milligram, Weekly (Qw)	Not Reported
	Orencia		S			Not Reported
	Prednisone		C	Oral		Not Reported
	Leflunomide		C			Not Reported
	Folic Acid		C	Oral	5 Milligram	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678298	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244196		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Disseminated	Hydroxychloroquine			S	Unknown	200 Milligram, Bid, Daily		Sun
	Prednisone			S	Unknown	5 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678709	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016085		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Skin; Fatigue; Pyrexia; Rash; Weight Decreased	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678744	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1224307		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycine Dihydratee			S	Oral	500 Mg D1 Then 250 Mg Per Day		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678760	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1777			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Etanercept	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678767	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3367094-00		80 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Anuria	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Dolquine			S	Unknown			Not Reported
	Dolquine			S	Unknown			Not Reported
	Metformina			C	Oral			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Acovil			C	Oral			Not Reported
	Ganfort			C	Ophthalmic			Not Reported
	Pantoprazol			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Simvastatina			C	Oral			Not Reported
	Tramadol + Paracetamol			C	Oral			Not Reported
	Ceftriaxona			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678845	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-018482		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Cortancyl			S	Oral	20 Milligram, Once A Day (10-20?G)		Not Reported

	Coversyl	S	Intracardiac	Unk		Not Reported
	Coversyl	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678871	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002655			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Upper Respiratory Tract Infection	Hydroxychloroquine			S				Concordia
	Bactrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679113	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003002035			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679121	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003002037			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679615	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020156142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Physical Health Deterioration; Mobility Decreased; Musculoskeletal Pain;	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Ciclosporin			S	Unknown			Not Reported
	Diclofenac Sodium			S	Oral			Not Reported

Nervousness; Pain; Pain In Extremity	Prednisone		S	Unknown	Not Reported
	Plaquenil Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679976	EXPEDITED (15-DAY)		HO, OT	DE-SANOFI-AVENTIS-2012SA019610		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Lip Disorder; Pigmentation Disorder; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Cyclophosphamide			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisolone			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680086	EXPEDITED (15-DAY)		DE, OT	FR-SGP-000004		59 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Mesenteric Vein Thrombosis; Multiple Organ Dysfunction Syndrome; Product Use In Unapproved Indication; Septic Shock	Methylprednisolone			S	Unknown			Sungen Pharma
	Methylprednisolone			S	Intravenous (not otherwise specified)			Sungen Pharma
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	0.6 G/M²		Not Reported
	Cyclophosphamide			S	Unknown	0.6 G/M²		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680375	NON-EXPEDITED			US-APPCO PHARMA LLC-2082959			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness	Hydroxychloroquine Sulfate			S				Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680511	NON-EXPEDITED			US-APPCO PHARMA LLC-2082963			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680526	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2020-13065		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Oral			Not Reported
	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Ferrous Fumarate			S	Unknown	Unknown		Not Reported
	Ferrous Fumarate;Folic Acid			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Humira	S	Subcutaneous	Unknown	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported

Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Palafer	S	Unknown	Unknown	Not Reported
Palafer Cf	S	Unknown	Unknown	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Teva Pantoprazole	S	Unknown		Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unknown	Not Reported
Celebrex	C	Oral		Not Reported
Celecoxib	C	Oral		Not Reported
Prednisone	C	Unknown	Intracardiac	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680759	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003661			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680864	EXPEDITED (15-DAY)		OT	NVSC2020CA096830		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Cyclosporine			S	Unknown			Novartis
	Neoral			S	Oral			Novartis
	Hydroxychloroquine Sulfate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Remicade			S	Unknown	3 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680902	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224376		46 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 400 Mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680984	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099621			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680985	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100529		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine Sulfate			S				Sanofi
	Paracetamol			S				Not Reported
	Arava			S		200 Mg, Qd		Sanofi
	Meloxicam			S				Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680986	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, 2 Every 1 Week		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680987	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099339		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S		25 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680988	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099287		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Arava			S				Sanofi
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Cymbalta			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680991	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099390			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680992	EXPEDITED (15-DAY)		HO	CA-SA-2020SA099085			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dehydration; Drug Ineffective	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Leflunomide			S		Unk		Sanofi
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680993	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680994	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk Unk, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Hydroxychloroquine Sulfate			S	Unknown			Sanofi

	Metformin Hydrochloride	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Sanofi
	Colchicine	S	Unknown	Not Reported
	Sitagliptin	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681011	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099608		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681360	EXPEDITED (15-DAY)		OT	NVSC2020CA102910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Cosentyx			S	Unknown	Unk		Novartis

	Cimzia		S	Subcutaneous	Single Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Otezla		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Stelera		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Arava		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681818	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019820		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ertapenem			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Aurobindo
	Piperacillin+Tazobactam 4/0.5g Powderforsolutionforinfusion			S	Intravenous (not otherwise specified)	Unk Unk, Once A Day		Aurobindo
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681820	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-019814		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo

	Azithromycin	S				Aurobindo
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone	S				Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681821	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019810		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17685294	DIRECT					52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Heart Rate Irregular; Palpitations; Pneumonia	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	18246779	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Azithromycin 500 Mg			S	Oral	500 Mg On First Day	4 DAY	Not Reported

	Hydroxychloroquine 400mg	S	Oral	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	11595241	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1641772		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Cystitis; Cystitis; Diarrhoea; Dizziness; Nausea; Pain; Pneumonia; Sensitivity To Weather Change; Swelling; Urinary Tract Infection	Esbriet			S	Oral			Not Reported
	Esbriet			S	Oral			Not Reported
	Esbriet			S	Unknown			Not Reported
	Esbriet			S	Unknown	Dose Increased To 9 Capsules A Day, Every 1 Day		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cephalexin [Cefalexin]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Unknown	Therapy Duration: 2 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	15292197	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-AUROBINDO-AUR-APL-2018-041851			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe Tablets			S	Transplacental	From Gestational Week 0-14		Aurobindo
	Pantoprazole			S	Transplacental	40 Milligram, Once A Day		Aurobindo
	Acetylsalicylic Acid			S	Transplacental	100 Milligram, Once A Day		Not Reported
	Ramipril			S	Transplacental	20 Milligram, Once A Day, From Gestational Week 0-113+6		Aurobindo
	Simvastatin Film-Coated Tablet			S	Transplacental	From Gestational Week 0-		Aurobindo

			14	
Aspirin	S	Transplacental	100 Milligram, Once A Day (From Gestational Week 0-14)	Not Reported
Aspirin	S			Not Reported
Aliskiren	S	Transplacental	300 Milligram, Once A Day	Not Reported
Hydroxychloroquine	S	Transplacental	400 Milligram, Once A Day	Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Prednisolone	S	Transplacental	10 Milligram, Two Times A Day From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Salbutamol	S	Transplacental	Unk, Once A Day,From Gestational Week 0-14	Not Reported
Tacrolimus	S	Transplacental	6 Milligram, Once A Day	Not Reported
Tacrolimus	S			Not Reported
Torasemide	S	Transplacental	100 Milligram, Once A Day	Not Reported
Heparin	S	Transplacental	Unk	Not Reported
Clexane	S	Transplacental	From Gestational Week 0-14	Not Reported
Clexane	S	Transplacental	200 Milligram, Once A Day	Not Reported
Dalteparin	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682209	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-019426		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682256	EXPEDITED (15-DAY)		HO, OT	SE-AUROBINDO-AUR-APL-2020-018861		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram		Aurobindo
	Prednisolone			S	Oral	10-15st.		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682362	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003499			Unknown	USA

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

Acute Promyelocytic Leukaemia; Neutropenia; Off Label Use; Thrombocytopenia	Hydroxychloroquine		S	Unknown	Unk	Concordia
	Methotrexate		S	Unknown	Unk	Not Reported
	Methylprednisolone		S	Unknown	Unk	Not Reported
	Immunoglobulin I.V		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682415	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-13043			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride			S	Unknown			Actavis
	Azathioprine			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Unknown			Duramed
	Methotrexate			S	Unknown			Barr
	Pantoprazole			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682516	EXPEDITED (15-DAY)		DE, OT	BR-ADVANZ PHARMA-202004002764			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682522	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223780			Female	CAN

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

Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride	S	Unknown	Not Reported
	Bisoprolol	S	Unknown	Duramed
	Methotrexate	S	Unknown	Barr
	Pantoprazole	S	Unknown	Actavis
	Prednisone	S	Unknown	Actavis
	Zopiclone	S	Unknown	Not Reported
	Cefixime	S	Unknown	Not Reported
	Imuran	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rivotril	S	Unknown	Not Reported
	Zantac	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682567	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202004003329			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia
	Euthyrox			S	Unknown	125 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682578	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004002839			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Infection; Joint Injury	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682710	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1223867		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Cymbalta			C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682746	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-018681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported

Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Once A Day	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682792	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2020-019423		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg D1 Then 250 Mg Per Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682818	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Q4wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Anakinra			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Benadryl [Acrivastine]			C	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Darifenacin			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Dilaudid			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Kadian			C	Unknown	Unk		Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Intra-articular	Unk		Not Reported
	Lasix [Furosemide]			C	Unknown	Unk		Not Reported

	Loperamide	C	Unknown	Unk	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Unk	Not Reported
	Omnaris	C	Unknown	Unk	Not Reported
	Orphenadrine Citrate	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Restasis	C	Unknown	Unk	Not Reported
	Rituximab	C	Intravenous drip	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Trimethoprim	C	Unknown	Unk	Not Reported
	Urispas	C	Unknown	Unk	Not Reported
	Vagifem	C	Vaginal	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682829	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031379			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Arava			S	Unknown	25 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15634974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105454			Female	CAN

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

Adverse Event; Ankylosing Spondylitis; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Orencia	S	Unknown	Unk		Bristol Myers Squibb
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown			Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Ciclosporin	S	Unknown			Not Reported
	Enbrel	S	Unknown	2.5 Milligram, Q2wk		Not Reported
	Enbrel	S	Subcutaneous	25 Milligram		Not Reported
	Infliximab	S	Unknown	25 Milligram		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15635082	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105542		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cardiac Disorder; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Anakinra	S	Unknown		Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported

Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Marijuana	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Rituximab	C	Unknown	Unk		Not Reported
Urelumab	C	Unknown	Unk		Not Reported
Lyrica	C	Oral			Not Reported
Prednisone	C	Unknown	Unk Unk, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Cannabis Sativa	S	Unknown			Not Reported
Xeljanz	S	Oral	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15840631	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16045300	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020351		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other	80 Milligram Daily;		Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16079806	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05468			Male	CAN

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

Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Clopidogrel Bisulfate	C	Oral	Unknown	Not Reported
	Ezetrol	C	Oral	Unknown	Not Reported
	Niaspan	C	Unknown	Unknown, Extended Release Tablet	Not Reported
	Nitroglycerin	C	Transdermal	Unknown	Not Reported
	Rosuvastatin Calcium	C	Oral	Unknown	Not Reported
	Tylenol	C	Oral	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16563279	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-17758		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting			otherwise specified)		
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown	Unknown, Other Route	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16936907	EXPEDITED (15-DAY)		CA, OT	DE-BAUSCH-BL-2019-057945		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Developmental Hip	Prednisolone			S	Transplacental	Maternal Dose: 5mg, Qd (One In One Day)		Not Reported
	Quensyl			S	Transplacental	Maternal Dose: 200		Not Reported

Dysplasia; Foetal Exposure During Pregnancy; Small For Dates Baby				(Mg/D)/Varying Dosage Between 150 And 200 Mg Daily	
	Mono-Embolex	C	Transplacental	Maternal Dose: 3000 (Ie/D)	Not Reported
	L-Thyroxin Jod Beta	C	Transplacental	Maternal Dose: 37.5 (Microg/D) / 75(Microg/D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17528005	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA067701		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Novartis
	Diclofenac			S	Oral	2 Df, Qd		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral			Novartis
	Diclofenac			S	Oral	Unk, Qd		Novartis
	Diclofenac			S	Oral	Unk		Novartis
	Pantoprazole			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Voltaren Sr			S	Oral	2 Df, Qd (75 Mg)		Not Reported
	Voltaren Sr			S	Oral	Unk		Not Reported
	Diclofenac Potassium			S	Oral			Novartis
	Cambia			S	Oral	Unk, Qd		Not Reported
	Cambia			S	Oral	Unk		Not Reported
	Cambia			S	Unknown	75 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	2 Df, Qd (1 Gram)		Not Reported

Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)		Not Reported
Pantoprazole Magnesium	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	1 Df, Qd		Not Reported
Synthyroid	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	2 Df, Qd		Not Reported
Gold	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17584672	EXPEDITED (15-DAY)		OT	NVSC2020US083168			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Gastrointestinal Pain; Joint Swelling	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17597328	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009074		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	25 Mg, Qd		Not Reported
Methotrexate	S	Unknown	15 Mg, Qd		Not Reported
Methotrexate	S	Endocervical	25 Mg, Qd		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Mg, Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Simponi	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17652112	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1218243		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Diastolic Dysfunction; Fluid Overload; Left Ventricular Dysfunction; Right Ventricular Dysfunction; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Initial Dosage Not Stated; Tit		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Rated To 200mg Twice Daily In The First Year		Teva
	Prednisone			C	Unknown			Not Reported
	Rituximab			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17675973	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA097041			Female	CAN

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

Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate	S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd		Sanofi
	Arava	S	Oral	10 Mg, Qd		Sanofi
	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Oral	25 Mg, Qw		Not Reported
	Methotrexate	S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide	S	Oral	10 Mg, Qd		Sanofi
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetylsalicylic Acid	C				Not Reported
	Asa	C	Unknown			Not Reported
	Calcium	C	Unknown			Not Reported
	Lantus	C	Subcutaneous			Not Reported
	Lozide [Gliclazide]	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17682990	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-12849		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported

Product Use Issue; Interstitial Lung Disease; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Esomeprazole Sodium	C	Unknown	Unknown	Not Reported
	Lumigan Rc	C	Ophthalmic	Unknown	Not Reported
	Lyrica	C	Unknown		Not Reported
	Sulfasalazin	C	Unknown		Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported
	Valsartan	C	Unknown	Unknown	Not Reported
	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683235	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004003379			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Oxygen Consumption Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Nicardipine			C		Unk		Not Reported
	Lovenox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683260	EXPEDITED (15-DAY)		HO	SE-TEVA-2020-SE-1224953		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15st.		Actavis
	Sertraline			S	Oral	750 Mg		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584741			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683398	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585127		38 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683443	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031020		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity;	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Actemra			S	Unknown	2.68 Milligram, Q4wk		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Q12h	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585203		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683494	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683881	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi

Osteomyelitis; Pain	Arava	S	Unknown	200 Mg, Qd	Sanofi
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown	5 Mg, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Acetaminophen	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100531		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Celecoxib			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683915	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099405			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft	Hydroxychloroquine Sulfate			S		Unk, Bid		Sanofi
	Actemra			S				Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Xeljanz			S				Not Reported

Tissue Swelling; Synovitis	Acetaminophen	C			Not Reported
	Ativan	C			Not Reported
	Anakinra	C		Unk	Not Reported
	Codeine	C			Not Reported
	Darifenacin	C			Not Reported
	Desoximetasone	C			Not Reported
	Dilaudid	C			Not Reported
	Diphenhydramine	C			Not Reported
	Hydromorphone	C			Not Reported
	Kadian	C			Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Suspension Intra-Articular	Not Reported
	Oxyneo	C			Not Reported
	Synthroid	C			Not Reported
	Urispas	C			Not Reported
	Trimethoprim	C			Not Reported
	Vagifem	C	Vaginal		Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683917	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099622			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			C		20 Mg, Qd		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C		3 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100527		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			C	Oral	1 G, Qd		Not Reported
	Xeljanz			C		5 Mg, Qd (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683921	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683934	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100245		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683935	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100641		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Hydroxychloroquine Sulfate			S		400 Mg, Qd (1 Every 1 Day)		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Rituximab			S		Unk		Not Reported

	Orencia	S	Not Reported
	Enbrel	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683939	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S		40 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585160			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Ciclosporin			S				Not Reported
	Imatinib			S	Unknown			Not Reported
	Imatinib			S				Not Reported

	Imatinib	S		Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Imuran [Azathioprine]	S		Not Reported
	Imuran [Azathioprine]	S		Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S		Not Reported
	Prednisone	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Tacrolimus	S		Not Reported
	Tacrolimus	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684002	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224352			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224903		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684130	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224385		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	80 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Ramipril			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224905		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684147	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Oral	1 Milligram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684161	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584882			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684208	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100329			Male	CAN

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

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Hydroxychloroquine	S		200 Mg, Qd	Sanofi
	Arava	S	Oral	20 Mg, Qd	Sanofi
	Actemra	S		200 Mg, Qm	Not Reported
	Enbrel	S			Not Reported
	Folic Acid	S		1 Mg, Qd	Not Reported
	Humira	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684211	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Diclofenac			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Arthrotec			C				Not Reported
	Desoximetasone			C				Not Reported
	Ibuprofen			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Oral	Unk Unk, Qd		Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C		Unk Unk, Qd		Not Reported
	Tramadol			C	Oral	Unk Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684214	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100514			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intestinal Perforation	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported

Methotrexate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Sanofi
Humira	S	Subcutaneous		Not Reported
Actemra	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684329	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224395			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Anxiety; Burning Sensation; Drug Ineffective; Hypoaesthesia; Infection; Juvenile Idiopathic Arthritis; Nausea; Neuropathy Peripheral	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celexa [Celecoxib]			C	Oral			Not Reported
	Cholecalciferol			C	Oral			Not Reported
	Ethinyl Estradiol/Norgestimate			C	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684330	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684454	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223977		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Stress	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Dequalinium Chloride			C				Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684459	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224366		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram Daily;		Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Oral			Not Reported
	Zopiclone			C	Unknown	7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224831		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract;	Leflunomide			S	Unknown			Barr

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Mobicox	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Other	80 Milligram Daily; Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684526	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224892		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Folic Acid	C	Unknown			Not Reported
Hydroxychloroquine Sulfate	C				Not Reported
Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684531	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684650	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224216			Female	CAN

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

Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide	S	Oral			Barr
	Methotrexate	S	Oral			Not Reported
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Lyrica	S	Oral	300 Milligram Daily;		Not Reported
	Acetaminophen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684658	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA100513			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S				Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported

Ilaris	S				Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Unk		Not Reported
Ilaris	S				Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098969		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Allopurinol			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Diclofenac Sodium			S	Topical	Solution Topical		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Diclofenac Potassium			S				Not Reported

Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Arava	S			Sanofi
	Arava	S		Unk	Sanofi
	Arava	S		Unk, Apo-Leflunomide, Tablet	Sanofi
	Naproxen	S			Not Reported
	Naproxen	S		Unk	Not Reported
	Naproxen	S		Unk, Apo-Naproxen	Not Reported
	Prednisone	S		5 Mg, Apo-Prednisone	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S		Unk, Winpred	Not Reported
	Celecoxib	S			Not Reported
	Celecoxib	S		Unk	Not Reported
	Celecoxib	S		Unk, Capsule	Not Reported
	Celecoxib	S		Unk, Capsule	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Misoprostol	S			Not Reported
	Pregabalin	S			Not Reported
	Sulfasalazine	S			Not Reported
	Amitriptyline	S			Not Reported
	Amitriptyline With Perphenazine	S			Not Reported
	Apo-Azathioprine	S			Not Reported
	Azathioprine	S			Not Reported
	Diclofenac Sodium And Misoprostol	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Etanercept	S			Not Reported
	Actemra	S			Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Lyrica	S			Not Reported
	Nifedipine	S			Not Reported

Orencia	S	Subcutaneous	750 Mg, Qw		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Mg		Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid		Not Reported
Tofacitinib	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684872	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1223974		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

	Urelumab			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685014	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100424		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Atenolol			C	Oral	50 Mg, Qd		Not Reported
	Hydrochlorothiazide			C		25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685016	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100528		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling;	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	14 Mg, Qd		Not Reported
	Arava			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qm		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Furosemide			C	Unknown	Unk Unk, Qd		Not Reported
	Hydromorph Contin			C		18 Mg, Tid, Sustained		Not Reported

Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Dilaudid		C	Unknown	Release 4 Mg, Tid	Not Reported
	Lyrica		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224477			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685109	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224361			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685110	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224214			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685113	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685114	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224837		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685278	EXPEDITED (15-DAY)		LT	CA-SAMSUNG BIOEPIS-SB-2020-13385			Female	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Anakinra	S				Not Reported
	Apo-Naproxen	S	Unknown	Unknown		Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Unknown, Solution		Not Reported
	Humira	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine	S	Oral	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone	S	Intra-articular	Unknown		Not Reported
	Triamcinolone	S				Not Reported
	Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224221		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased; Rheumatoid	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

Arthritis	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685527	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685606	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13343		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective For Unapproved Indication;	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Unknown	Not Reported
	Methotrexate		S	Oral	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Varicella-Zoster Immune Globulin		S	Subcutaneous	Liquid Intramuscular, Dose: Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685629	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223866		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685690	EXPEDITED (15-DAY)		OT	NVSC2020GB104678			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685725	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX008388		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified		Baxter
	Mycophenolate Mofetil			S	Unknown	Dosage Form: Not Specified		Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Plaquenil			S	Unknown	Dosage Form: Tablet		Not Reported
	Rituxan			S	Unknown	Dosage Form: Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			C	Unknown	Dosage Form: Not Specified		Not Reported
	Domperidone			C	Unknown	Dosage Form: Tablet		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685734	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224445			Female	CAN

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

Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Leflunomide	S	Oral	10 Milligram Daily;	Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Leucovorin	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	C			Not Reported
	Calcium Citrate; Magnesium Citrate	C			Not Reported
	Citalopram Hydrobromide	C			Not Reported
	Clobetasol Propionate	C	Topical		Not Reported
	Naproxen	C	Oral		Not Reported
	Pantoprazole Magnesium	C			Not Reported
	Escitalopram Oxalate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685735	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224422		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Azathioprine Sodium			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685788	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223967			Female	CAN

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

Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	4800 Milligram Daily;		Not Reported
	Kevzara	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685791	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224383			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685813	EXPEDITED (15-DAY)		DE	ES-ASTRAZENECA-2020SE51307		95 YR	Female	ESP

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

Sudden Death	Quetiapine		S	Oral		Zeneca
	Hydroxychloroquine Sulphate		S	Oral		Not Reported
	Levofloxacin		S	Intravenous (not otherwise specified)		Not Reported
	Kaletra		S	Oral	200/50 Mg, 2 Df Daily, 120 Tablets	Not Reported
	Risperidone		S	Oral		Not Reported
	Losartan		C	Oral		Not Reported
	Clindamycin Hydrochloride		C	Intravenous (not otherwise specified)		Not Reported
	Lorazepam		C	Oral		Not Reported
	Furosemide		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685815	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12772		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown,		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not	Unknown,		Not Reported

			otherwise specified)			
	Sulfasalazine	S	Oral			Not Reported
	Sulfasalazine	S	Oral	Unknown		Not Reported
	Acetaminophen/Oxycodone Hydrochloride	C	Unknown	Unknown		Not Reported
	Celebrex	C	Oral	Unknown		Not Reported
	Furosemide	C	Unknown	Unknown		Not Reported
	Morphine	C	Unknown	Unknown		Not Reported
	Oxycodone Terephthalate	C	Unknown	Unknown		Not Reported
	Ramipril	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685895	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224217			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685905	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223975		51 YR	Male	CAN

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

Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Methotrexate	S	Unknown		Barr
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram Daily;	Not Reported
	Sulfasalazine	S	Unknown	1 Gram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Unknown	15 Milligram Daily;	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685927	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224413			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Depo-Medrol			C	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685928	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223947			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685929	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative Arthritis; Urinary Tract Obstruction	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685981	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224403			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Remicade			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685990	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223963			Male	CAN

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

C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Leflunomide	S	Oral	20 Milligram Daily;		Barr
	Leflunomide	S	Oral	10 Milligram Daily;		Barr
	Prednisone	S	Unknown			Actavis
	Methotrexate	S	Oral			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686061	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223940			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)			
	Remicade		S				Not Reported
	Rituximab		S	Unknown			Not Reported
	Rituximab		S				Not Reported
	Sulfasalazine		S	Unknown			Not Reported
	Sulfasalazine		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686242	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-13015		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Myochrysine	S	Intramuscular			Not Reported
Orencia	S	Unknown			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Ciclosporin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686331	EXPEDITED (15-DAY)		OT	NVSC2020CA105008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plantago Afra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			C	Subcutaneous	22.5 Mg, Qw		Not Reported
	Folic Acid			C	Unknown	5 Mg		Not Reported
	Ergocalciferol			C	Unknown	2000 Iu, Qd		Not Reported
	Cannabis Sativa			C	Unknown	Unk Unk, Qd		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686344	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3365681-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Back Pain; Chest Pain; Cough; Diarrhoea; Drug Ineffective; Eye Irritation; Headache; Musculoskeletal Pain; Nasopharyngitis; Pleural Effusion; Pyrexia; Retinal Injury; Rhinorrhoea	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686431	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004003537			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Vision Loss; Macular Degeneration; Maculopathy; Retinal Toxicity; Retinopathy; Vision Blurred	Hydroxychloroquine			S		800 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686581	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-018504		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Ambisome			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686584	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018508		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17690121	DIRECT		HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	400mg Bid For 1 Day Then 200bid For 1 Day Bid Po X 1 Day(S)		Not Reported
	Azithromycin			S		500mg Qd X 1 250mg Daily For 3 Days Qd Po X 3 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15163376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2154400		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15418599	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20180917519		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Ciclosporin			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported

Methotrexate	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Methotrexate Sodium	S	Subcutaneous			Not Reported
Neoral	S	Oral			Not Reported
Neoral	S	Subcutaneous			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Oral			Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Oral	2 Ot		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15680209	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574019-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15702743	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2581224-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Marijuana			C				Not Reported
	Risedronate			C	Oral			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Bupropion			C	Unknown			Not Reported
	Cannabis Sativa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16640871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-070998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16724652	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA192974		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Voltaren			S	Unknown			Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Clopidogrel			S	Unknown	Unk		Not Reported
	Clopidogrel			S				Not Reported
	Clopidogrel			S				Not Reported
	Clopidogrel			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Vitamin C			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Asa			S	Unknown	325 Mg (Delayed Release)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Gold	S			Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Topical		Not Reported
Aspirin	S	Unknown		Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Ibuprofen	S	Unknown		Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Trimethoprim	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16841034	EXPEDITED (15-DAY)		OT	GR-BAUSCH-BL-2019-026015		59 YR	Female	GRC

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

Secondary; Osteoporosis; Rib Fracture; Upper Respiratory Tract Infection	Prednisolone		S	Unknown	Bausch And Lomb
	Metformin Hydrochloride		S	Unknown	Santarus
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Lansoprazole		S	Unknown	Not Reported
	Belimumab		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Exemestane		S	Unknown	Not Reported
	Thyroxine		S	Oral	Not Reported
	Thyroxine		S	Unknown	Not Reported
	Dicumarol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	6965678	EXPEDITED (15-DAY)		OT	DE-RANBAXY-2009RR-23202		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome	Ceftriaxone			S	Unknown	Unk		Not Reported
	Co-Trimoxazole			S	Unknown	Unk		Mutual
	Doxycycline Hydrochloride			S	Unknown	Unk		Sun
	Hydroxycholoroquine Sulphate-Bp			S	Unknown	Unk		Sun
	Streptomycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579772	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327858		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17616081	EXPEDITED (15-DAY)		DE, HO	BR-ADVANZ PHARMA-202003002042			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623454	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340457		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Ebastine	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623532	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340124		64 YR	Female	CAN

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

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Cyclobenzaprine	C	Oral	Not Reported
Cyclobenzaprine	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Leflunomide	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone Acetate	C	Unknown	Not Reported
Tylenol /00020001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623533	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340125		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Asa			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Ultracet			C				Not Reported
	Calcite D			C	Unknown			Not Reported
	Citalopram			C				Not Reported

Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Domperidone	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Gabapentin	C		Not Reported
	Gliclazide	C	Unknown	Not Reported
	Lipitor	C		Not Reported
	Nifedipine	C		Not Reported
	Pantoloc /01263204/	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Risedronate	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340129		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Penicilline G /00000901/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17666231	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029672		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17681010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi

	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Naproxen	C	Unknown	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686802	EXPEDITED (15-DAY)		OT	JP-LAURUS LABS LIMITED-202000088		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Placenta Accreta	Hydroxychloroquine			S	Unknown			Unknown
	Prednisolone			C	Unknown			Not Reported
	Tacrolimus			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686999	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585020		70 YR	Female	CAN

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

Lyrica	C		Not Reported
Prednisone	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687219	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244391			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687411	EXPEDITED (15-DAY)		OT	DE-TEVA-2020-DE-1224814		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma Skin; Mycobacterium Marinum Infection	Leflunomide			S	Unknown			Barr
	Prednisolone			S	Unknown	Low-Dose		Actavis
	Prednisolone			S	Unknown			Actavis
	Prednisolone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Sulfasalazine			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687714	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100422		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy;	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi

Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Arava	S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate	S	Subcutaneous	20 Mg, Qw		Not Reported
	Prednisone	S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	50 Mg, Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	20 Mg, Qd		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Arava			S				Sanofi
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687718	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition	Hydroxychloroquine			S				Sanofi

Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Arava	S				Sanofi
	Celecoxib	S	Oral	200 Mg, Bid		Not Reported
	Actemra	S				Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S				Not Reported
	Rituximab	S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687792	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100987			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Plaquenil			S	Unknown			Sanofi
	Aralen			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687797	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA101046		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific	Hydroxychloroquine Sulfate			S	Oral	5 Mg		Sanofi
	Methotrexate			S		15 Mg/M2, Qow		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S				Sanofi

Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd		Not Reported
	Anakinra	S	Unknown	50 Mg, Qd		Not Reported
	Enbrel	S		1.5 Mg, Qw		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	30 Mg, Qw		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Triamcinolone Hexacetonide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687801	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688091	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1040433		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Compartment Syndrome; Acute Respiratory Distress Syndrome; Drug Ineffective; Pancreatitis Necrotising; Sepsis; Shock Haemorrhagic	Prednisolone			S	Intravenous (not otherwise specified)	Pulse Therapy		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Plasma			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584496		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688210	EXPEDITED (15-DAY)		OT	NVSC2020IT104815		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Interaction; Hepatic Failure; Pneumonia Viral; Product Use In	Tacrolimus			S	Unknown	Unk		Novartis
	Tacrolimus			S				Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported

Unapproved Indication	Hydroxychloroquine Sulfate	S				Not Reported
	Ritonavir	S	Unknown	Unk		Not Reported
	Ritonavir	S				Not Reported
	Mycophenolate Mofetil	C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil	C				Not Reported
	Darunavir	C	Unknown	Unk		Not Reported
	Darunavir	C				Not Reported
	Cobicistat	C	Unknown	Unk		Not Reported
	Cobicistat	C				Not Reported
	Colchicine	C	Unknown	1 Mg On Day 8		Not Reported
	Colchicine	C	Unknown	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688319	NON-EXPEDITED			US-CELGENEUS-USA-20200404981			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diarrhoea; Headache	Otezla			S	Oral	60 Milligram		Celgene
	Synthroid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cosentyx			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Effexor			C	Unknown			Not Reported
	Baby Aspirin			C	Unknown			Not Reported
	Prilosec			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Femara			C	Unknown			Not Reported
	Prozosin			C	Unknown			Not Reported

	Meloxicam	C	Unknown	Not Reported
	Doxorubicin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688648	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1225642		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Hidroxicloroquina (2143a)			S	Oral	400mg/24h		Teva
	Linezolid (1279a)			S	Intravenous (not otherwise specified)			Teva
	Ambisome 50 Mg Polvo Para Dispersion Para Perfusion , 10 Viales			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688686	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13364		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported

Sulfasalazine	S	Oral	Unknown		Not Reported
Tocilizumab	S	Unknown	Unknown		Not Reported
Desoximetasone	C	Unknown	Unknown		Not Reported
Methotrexate	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688704	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004002845			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Blindness; Cataract	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd (Coated Tablet)		Concordia
	Depakote			C		Unk		Not Reported
	Ozempic			C		Unk		Not Reported
	Selozok			C		Unk		Not Reported
	Pressetina			C		Unk		Not Reported
	Glifage			C		Unk		Not Reported
	Zetia			C		Unk		Not Reported
	Rosuvastatina			C		Unk		Not Reported
	Marevan			C		Unk		Not Reported
	Topiramato			C		Unk		Not Reported
	Venlafaxine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688866	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100693			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi

Fluctuation; Therapeutic Product Effect Incomplete	Arava	S				Sanofi
	Bisoprolol Salt Not Specified	S				Not Reported
	Cefaclor	S				Not Reported
	Celecoxib	S	Oral	200 Mg, Qd (1 Df, Every 1 Day)		Not Reported
	Demerol	S				Sanofi
	Erythromycin	S				Sanofi
	Erythromycin	S				Sanofi
	Levofloxacin	S				Not Reported
	Pregabalin	S				Not Reported
	Methotrexate	S				Not Reported
	Metronidazole	S				Sanofi
	Norfloxacin	S				Not Reported
	Prednisone	S				Not Reported
	Sulfasalazine	S				Not Reported
	Arthrotec	S				Not Reported
	Humira	S	Subcutaneous	400 Mg		Not Reported
	Meperidine Hydrochloride	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100853			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S	Unknown			Sanofi
	Aralen			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688872	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100674		32 YR	Female	CAN

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

Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Hydroxychloroquine	S				Sanofi
	Methotrexate	S				Not Reported
	Leflunomide	S				Sanofi
	Orencia	S				Not Reported
	Xeljanz	S				Not Reported
	Actemra	S	Subcutaneous	162 Mg, Qw		Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydrocortisone	C		Unk Unk, Bid		Not Reported
	Pantoloc [Pantoprazole]	C				Not Reported
	Prednisone	C		20 Mg, Qd		Not Reported
	Xarelto	C				Not Reported
	Tylenol 8 Hr Arthritis Pain	C		2 Df, Bid		Not Reported
	Calcium & Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688898	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown; Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown; Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported

	Methotrexate	C	Oral			Not Reported
	Desoximetasone	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688907	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101008		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Unk		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Xeljanz			S	Oral	5 Mg		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100917			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S		50 Mg,Qw		Not Reported
	Myochrysine			S		25 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689015	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Sudden Death	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689055	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226544		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Oral			Teva
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689154	EXPEDITED (15-DAY)		CA, DS, OT	FR-UCBSA-8027844			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Keppra			S		3000mg Daily		Not Reported
	Keppra			S	Transplacental	Unk		Not Reported
	Trileptal			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Paracetamol			S	Transplacental			Not Reported
	Cortancyl			C	Transplacental			Not Reported
	Actonel			C	Transplacental			Not Reported
	Orocal D3			C	Transplacental			Not Reported
	Diffu-K			C	Transplacental			Not Reported
	Speciafoldine			C	Transplacental			Not Reported
	Kaleorid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225072			Female	CAN

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

Drug Ineffective; Neutropenia; Rash; White Blood Cell Count Decreased	Leflunomide		S	Unknown	20 Milligram Daily;	Barr
	Methotrexate		S	Unknown	20 Mg, 1 Every 1 Week	Barr
	Plaquenil		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689616	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Morphine Sulfate			S	Unknown			Actavis
	Prednisone			S	Unknown	12.5 Milligram Daily;		Actavis
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689685	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226003		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Amoxixilina / Clavulanico (Amoxicillin\Clavulanic Acid)			S	Oral	875 Mg,1 Df		Teva

	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;		Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689693	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016133US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Azithromycine Sandoz [Azithromycin Monohydrate]			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101218			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S				Sanofi
	Bisoprolol Fumarate			S				Not Reported
	Cefixime			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine Hydrochloride			S				Not Reported
	Nifedipine			S				Not Reported
	Pantoprazole			S				Not Reported
	Prednisone			S				Not Reported
	Clonazepam			S				Not Reported
	Zantac			S				Sanofi
	Zopiclone			S				Not Reported
	Azathioprine			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689717	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride			S				Not Reported
	Penicillin G [Benzylpenicillin]			S				Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qm, Solution Subcutaneous		Not Reported
	Stelara			S		Unk, Q8w		Not Reported
	Stelara			S	Subcutaneous	Unk, Solution Subcutaneous		Not Reported
	Cetirizine			C		10 Mg, Bid		Not Reported

Enbrel	C	50 Mg, Qw	Not Reported
Lasix [Furosemide]	C	40 Mg, Qm	Not Reported
Montelukast	C	10 Mg, Qd	Not Reported
Synthroid	C	75 Mg, Qd	Not Reported
Terbutaline Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689729	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	1 Df, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689734	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101213		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported
	Orencia			S	Unknown			Not Reported

Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Acetaminophen	C			Not Reported
	Anakinra	C	Unknown	100 Mg	Not Reported
	Ativan	C			Not Reported
	Codeine	C			Not Reported
	Darifenacine	C			Not Reported
	Desoximetasone	C			Not Reported
	Dilaudid	C			Not Reported
	Diphenhydramine	C			Not Reported
	Furosemide	C			Not Reported
	Hydromorphone	C			Not Reported
	Kadian	C			Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	40 Mg	Not Reported
	Loperamide	C			Not Reported
	Norflex [Orphenadrine Citrate]	C			Not Reported
	Omnaris	C			Not Reported
	Oxyneo	C			Not Reported
	Pantoprazole	C			Not Reported
	Restasis	C			Not Reported
	Rituximab	C	Intravenous (not otherwise specified)		Not Reported
	Synthroid	C			Not Reported
	Trimethoprim	C			Not Reported
	Urispas	C	Unknown	200 Mg	Not Reported
	Vagifem	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689790	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225158		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methotrexate	S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Mobicox	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Depo-Medrol	C		80 Milligram Daily; Suspension Intraarticular		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689979	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2609900-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690106	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA102627		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690600	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-019705		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690705	EXPEDITED (15-DAY)		HO	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244413		35 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rash	Ciprofloxacin			S	Unknown	800 Milligram, Daily		Ranbaxy
	Doxycycline			S	Oral	Unk		Sun
	Hydroxychloroquine			S	Oral	600 Milligram, Daily		Sun
	Moxifloxacin			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226789		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate			S	Oral			Teva
	Risedronate			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	13319448	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902949			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Powder For Suspension		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	14999486	EXPEDITED (15-DAY)		DE, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-175486		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Lorazepam			S	Unknown	Unk ()		Sun
	Montelukast			S	Unknown	Unk ()		Not Reported
	Celecoxib			S	Unknown	Unk ()		Not Reported
	Warfarin			S	Unknown	Regimen 1 ()		Not Reported
	Influenza Vaccine Inactivated			S	Unknown	Unk ()		Not Reported
	Asa			S	Endocervical	Unk ()		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk ()		Not Reported
	Hydroxychloroquine			S	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15268901	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168136			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Clavulanate Potassium			C						Not Reported
	Amoxil [Amoxicillin]			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15360741	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-TORRENT-00009759			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Unknown
	Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Unknown
	Clexane			S	Transplacental	Exposure Duration: 0-14 Weeks		Unknown
	Dalteparin Sodium			S	Transplacental	Unknown		Unknown
	Enoxaparin Sodium			S	Transplacental	From Gestational Week 0-14		Unknown
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Unknown
	Heparin			S	Transplacental	Unknown		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Unknown
	Metamizole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Unknown
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Unknown
	Ramipril			S	Transplacental	20 Mg Per Day, Exposure Duration: 0-113+6 Weeks / Maternal Dose 20 Mg, Unknown		Not Reported
	Rituximab			S	Transplacental	Unk, Last Time In		Unknown

				December 2011: Pre Or Periconceptional	
	Salbutamol	S	Transplacental	From Gestational Week 0-14	Unknown
	Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Tacrolimus	S	Transplacental	From Gestational Week 0-14	Unknown
	Torsemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5	Unknown
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
	Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15624422	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556711-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Warfarin	S	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15629635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557205-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; General Physical Health Deterioration; Knee Arthroplasty; Rheumatoid Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15668157	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570296-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance;	Humira			S	Subcutaneous			Not Reported

Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arthrotec	S	Unknown		Not Reported
	Bisoprolol	S	Unknown		Not Reported
	Ceclor	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Demerol	S	Unknown		Not Reported
	Erythro Base	S	Unknown		Not Reported
	Erythromycin Estolate	S	Unknown		Not Reported
	Levofloxacin Hemihydrate	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Meperidine Hydrochloride	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Metronidazole	S	Intravenous (not otherwise specified)	Dosage Form-Liquid Intravenous	Not Reported
	Norfloxacin	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Erythromycin	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Levofloxacin	S	Unknown		Not Reported
	Bisoprolol Fumarate	S	Unknown		Not Reported
	Celecoxib	S	Oral		Not Reported
	Meperidine	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Cefaclor	S	Unknown		Not Reported
	Leflunomide Sandoz	S	Unknown		Not Reported
	Noritate	S	Unknown		Not Reported

Plaquenil	S	Oral			Not Reported
Act Diclo Miso	S	Unknown	Enteric Coated		Not Reported
Diclofenac + Misoprostol Aurovitas	S	Unknown			Not Reported
Methotrexate Sodium	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16080823	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013796		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib			S				Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Milliliter, Every Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

	Celebrex		S	Unknown	Unk	Not Reported
	Cimzia		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16639635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2867070-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Sulfasalazin			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17531498	EXPEDITED (15-DAY)		DS, HO, OT	CA-GLAXOSMITHKLINE-CA2020044221		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Glaxosmithkline
	Diclofenac			S	Oral	2 Df, Qd		Glaxosmithkline
	Diclofenac			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac			S	Oral	Unk, Qd		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Oral	Unk		Glaxosmithkline

	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Voltaren Sr	S	Oral	2 Df, Qd (75 Mg)	Glaxosmithkline
	Voltaren Sr	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Cambia	S	Oral	Unk, Qd	Glaxosmithkline
	Cambia	S	Oral	Unk	Glaxosmithkline
	Cambia	S	Unknown	75 Mg, Bid	Glaxosmithkline
	Lisinopril	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)	Not Reported
	Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)	Not Reported
	Plaquenil	S	Oral	1 Df, Qd	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	2 Df, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690794	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226002		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	200 Milligram Daily; 200 Mg/24h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; 600mg/24h		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690973	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001159			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Gastrointestinal Disorder;	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Not Reported

Headache; Nausea; Urinary Tract Infection	Prednisolone	S	Unknown	20 Milligram, Qd	Not Reported
	Prednisolone	S	Unknown	9 Milligram, Qd	Not Reported
	Amoxicillin	S	Unknown	Unk	Not Reported
	Amoxicillin	S			Not Reported
	Co-Amoxiclav	S	Unknown	Unk	Not Reported
	Gentamycin	S	Unknown	Unk	Not Reported
	Tobramycin	S	Unknown	Unk	Not Reported
	Colomycin [Colistimethate Sodium]	S	Unknown	Unk	Not Reported
	Doxycycline	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Meropenem	S	Unknown	Unk	Not Reported
	Tazobactam/Piperallin	S	Unknown	Unk	Not Reported
	Ceftazidime	S	Unknown	Unk	Not Reported
	Cefradine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691161	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	7.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	7.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20.0 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Diclofenac Sodium And Misoprostol			S		50 Mg, Bid		Not Reported
	Arthrotec			C		50 Mg, Bid		Not Reported
	Gold			C				Not Reported
	Imuran [Azathioprine]			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691425	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225669		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Does 500 Mg		Not Reported
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Dose 250 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h, Unit Dose 2 Gm		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691428	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA104277		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone			S				Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691526	EXPEDITED (15-DAY)		HO, LT	SI-ABBVIE-20K-261-3372991-00		48 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Thrombocytopenia	Kaletra			S	Oral	(80mg+20mg)/Ml Oral Solution, Dose 400mg/100 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Esmeron			C				Not Reported
	Metoclopramid			C				Not Reported
	Analgin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691915	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584504			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692427	EXPEDITED (15-DAY)		OT	CN-ADVANZ PHARMA-202004003310			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692563	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004003424			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome;	Hydroxychloroquine			S		600 Mg, Qd Film-Coated Tablet		Concordia

Off Label Use; Overdose; Pneumonia Bacterial; Septic Shock	Hydroxychloroquine	S	400 Mg, Qd Film-Coated Tablet	Concordia
	Hydroxychloroquine	S	200 Mg, Qd Film-Coated Tablet	Concordia
	Hydroxychloroquine	S	400 Mg, Qd Film-Coated Tablet	Concordia
	Cefepim Amomed	C	Unk	Not Reported
	Midazolam	C	Unk	Not Reported
	Sufentanil	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported
	Atracurium Besilate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692890	NON-EXPEDITED			US-AMGEN-USASP2020063491		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Eye Disorder; Injection Site Pain; Pain; Sinusitis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692900	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003924		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Quetiapine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported

	Ritonavir/Lopinavir	S	Oral	Not Reported
	Losartan	C	Oral	Not Reported
	Clindamycin Hydrochloride	C	Intravenous (not otherwise specified)	Not Reported
	Lorazepam	C	Oral	Not Reported
	Furosemide	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692945	EXPEDITED (15-DAY)		OT	CN-ADVANZ PHARMA-202004003226			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Liver Injury; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693787	EXPEDITED (15-DAY)		DE, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032939		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Rituximab;Urelumab	C	Unknown		Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693828	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre Filled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693966	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419466		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17694029	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225643		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	1er Día 400 Mg/12 H, A Partir Del 2º Día 400mg/24 H		Teva
	Azitromicina (7019a)			S	Oral	500 Mg 1st Dose, Later 250mg / 24h		Not Reported
	Azitromicina (7019a)			S	Oral			Not Reported

	Tocilizumab (8289a)		S	Intravenous (not otherwise specified)	600 Milligram Daily; Single Dose	Not Reported
	Tocilizumab (8289a)		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17694856	EXPEDITED (15-DAY)		LT	FR-ELI_LILLY_AND_COMPANY-FR202004008033		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg, Daily		Eli Lilly And Co
	Plaquenil Sulfate			S	Oral	800 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17695215	EXPEDITED (15-DAY)		DE	IT-AUROBINDO-AUR-APL-2020-019985		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17695429	EXPEDITED (15-DAY)		HO	DE-BAXTER-2020BAX008027		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Epidermal Necrosis; Lip Disorder; Lip Disorder; Pigmentation Disorder; Skin Lesion; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis	Endoxan Lyophilisat			S	Unknown			Baxter
	Leflunomide			S	Unknown			Not Reported
	Trimethoprim/Sulfamethoxazole			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisolone			S	Nasal			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	13665971	EXPEDITED (15-DAY)		OT	TN-BAUSCH-BL-2017-019520		33 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	13974821	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

					otherwise specified)					
	Prednisone			S	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14497211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported

	Hydromorphone	C	Unknown	Unk		Not Reported
	Synthroid	C	Unknown	Unk		Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16731204	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019152774		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Voltaren(Diclofenac)			S	Unknown	Unk		Glaxosmithkline
	Voltaren(Diclofenac)			S				Glaxosmithkline
	Voltaren(Diclofenac)			S				Glaxosmithkline
	Voltaren(Diclofenac)			S				Glaxosmithkline
	Vitamin C			S	Unknown	Unk		Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Aspirin			S	Unknown	Unk		Glaxosmithkline
	Aspirin			S				Glaxosmithkline
	Aspirin			S				Glaxosmithkline
	Aspirin			S				Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Clopidogrel			S	Unknown	Unk		Glaxosmithkline
	Clopidogrel			S				Glaxosmithkline
	Clopidogrel			S				Glaxosmithkline
	Clopidogrel			S				Glaxosmithkline
	Ibuprofen			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole			S	Unknown	Unk		Glaxosmithkline
	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported

Asa	S	Unknown	325 Mg (Delayed Release)		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S				Not Reported
Methotrexate	S				Not Reported
Methotrexate	S				Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S				Not Reported
Humira	S				Not Reported
Humira	S				Not Reported
Plaquenil	S	Oral	Unk		Not Reported
Plaquenil	S				Not Reported
Plaquenil	S				Not Reported
Plaquenil	S				Not Reported
Apo-Diclofenac	S	Topical	Unk		Not Reported
Naproxen	S	Unknown	Unk		Not Reported
Naproxen	S				Not Reported
Naproxen	S				Not Reported
Naproxen	S				Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk		Not Reported
Tramadol	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Trimethoprim	S	Unknown	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Gold	S				Not Reported
Gold	S				Not Reported
Gold	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16748699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2381845		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Mycophenolate Mofetil	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17035098	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136345		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Prednisone			S	Oral	20 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
Rituximab	S	Unknown	2000 Milligram Daily;		Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
Rituxan	S	Unknown	2 Gram Daily;		Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;		Not Reported
Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17191010	EXPEDITED (15-DAY)		OT	NVSC2019CA076411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg Solution		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

Methotrexate	S	Intra-arterial	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk		Not Reported
Cetirizine Hydrochloride	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Arava	S	Oral	Unk		Not Reported
Cortisone Acetate	S	Topical	25 Mg		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Subcutaneous	500 Mg		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17666050	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3361715-00		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17667413	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000290			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Furosemide			S	Intravenous (not otherwise specified)	2 Df, Qd		Validus
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Perfalgan			C		Unk		Not Reported
	Noradrenalin /00127501/			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Tazocilline			C		Unk		Not Reported
	Transipeg /00754501/			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Nimbex /01302502/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17695364	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020073		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696576	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1224670		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Prednisone			S	Unknown	5 Milligram Daily; Daily		Actavis
	Acetaminophen			C	Unknown	Estimated 6g		Not Reported
	Metronidazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696653	EXPEDITED (15-DAY)		LT	CA-ROCHE-2585146		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Procytox			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696778	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696808	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3374580-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Dolquine			S	Oral			Not Reported
	Levofloxacino			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585673		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease;	Rituximab			S	Unknown			Not Reported

Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Mycophenolate Mofetil	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
	Amoxicillin;Clavulanate Potassium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696968	EXPEDITED (15-DAY)		HO	CA-ROCHE-2585153		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported

	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697203	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020068659		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Codeine			S	Unknown	Unk		Glaxosmithkline
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia (Certolizumab Pegol)			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697218	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2020ES02876			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Milligram, Qd (Per Day; 500 Mg/24h)		Cipla

	Dolquine	S	Oral	200 Milligram, Per Day (1 Comp/24h)	Not Reported
	Metronidazol [Metronidazole]	S	Oral	Unk	Not Reported
	Amoxicilina + Acido Clavulonico	S	Oral	Unk, Tid (1 Comp/8h)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697219	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226965		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697355	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported

Pneumonia	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697469	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226211		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697552	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA101001		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased;	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	12 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported

Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer; Unevaluable Event	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S		12.5mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg Qw	Not Reported
	Methotrexate	S	Oral	10 Mg Qw	Not Reported
	Methotrexate	S		70.0 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		12.0 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qow	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Alendronate Sodium	S		70 Mg, Qw	Not Reported
	Leflunomide	S			Sanofi
	Leflunomide	S	Oral		Sanofi
	Sulfasalazine	S		500 Mg	Not Reported
	Codeine	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg, Qm	Not Reported
	Actemra	S		360 Mg	Not Reported
	Actemra	S		360 Mg	Not Reported
	Actemra	S		360 Mg, Qm	Not Reported
	Actemra	S		2.68 Mg, Q4w	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Enbrel	S		25 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		780 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	1000 Mg, Q12h	Not Reported
	Ciclosporin		C			Not Reported
	Prednisone		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697667	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226215		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697751	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226514		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr

Methotrexate	S	Subcutaneous	12.5 Milligram Daily;		Barr
Actemra	S	Intravenous (not otherwise specified)			Not Reported
Anakinra	S	Subcutaneous	100 Milligram Daily;		Not Reported
Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
Orencia	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698407	EXPEDITED (15-DAY)		DE, OT	ES-FRESENIUS KABI-FK202003872		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unk		Fresenius Medical Care
	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral	400mg/24h		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698625	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Therapeutic Product Effect Incomplete	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698783	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1226193		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Aleve			C	Unknown			Not Reported

	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699111	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226577			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699160	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101058			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis;	Arava			S		Unk		Sanofi
	Colchicine			S				Not Reported
	Celecoxib			S				Not Reported
	Estradiol			S	Topical	Unk Unk, Qd		Not Reported
	Prednisone			S		50 Mg		Not Reported

Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Meloxicam	S				Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil	S		2 Df, Qd		Sanofi
	Salbutamol Sulfate	S				Not Reported
	Sulfasalazine	S				Not Reported
	Belimumab	S				Not Reported
	Breo Ellipta	S	Respiratory (inhalation)			Not Reported
	Dexilant	S	Oral	60 Mg, Qd		Not Reported
	Rituximab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585610		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699673	NON-EXPEDITED			US-APPCO PHARMA LLC-2083078		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699823	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226217		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Wellbutrin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226721		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

	Plaquenil[Hydroxychloroquine Phosphate]	C	Oral	400 Milligram Daily;	Not Reported
	Xeljanz	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226428		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Secretion Discharge; Spinal Stenosis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699865	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226602		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699945	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226474		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Acetaminophen	C	Unknown	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Elavil	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Imitrex [Sumatriptan]	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Sumatriptan Succinate	C	Unknown	Not Reported
Tenormin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699946	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226195			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17700384	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003668			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Narcan			S		Unk		Not Reported
	Cyclobenzaprine Hcl			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Wellbutrin Xl			S		Er 24h		Not Reported
	Wellbutrin Xl			S		Er 24h		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17700739	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020169		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haemolytic Anaemia; Hepatitis; Hyperbilirubinaemia; Rectal Haemorrhage	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17702515	EXPEDITED (15-DAY)		LT	FR-BAUSCH-BL-2020-011521		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral			Not Reported
	Loxapine Base			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Nicopatch			C	Transdermal	Transdermal Device Of 17.5 Mg / 10 Cm2		Not Reported
	Diazepam			C	Oral			Not Reported
	Atorvastatine			C	Oral			Not Reported
	Nicotine			C	Oral			Not Reported
	Macrogol 4000			C	Oral			Not Reported
	Nebivolol			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Akineton			C	Oral			Not Reported
	Ezetimibe			C	Oral			Not Reported
	Kardegic			C	Oral	Sachet Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703331	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness;	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported

Rheumatoid Arthritis; Vomiting	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703332	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703341	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Pariet			C	Unknown	20 Milligram, Qd		Not Reported
	Folic Acid			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703445	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226725		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Zopiclone	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17704032	DIRECT	Y	OT			32 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	12791907	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016449402		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		7.5 Mg, Every 10 Days		Pfizer
	Certolizumab Pegol			S		200 Mg, Every Other Week		Not Reported
	Certolizumab Pegol			S		Tapered To One Injection Every 21 Days		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13091523	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13856327	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070350		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Mellitus	Cortisone Acetate	S	Unknown		Not Reported
	Diclofenac	S	Unknown	50 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
	Arava	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14757587	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009591			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Desoximetasone	C	Unknown	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14951428	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018213596		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity	Docetaxel			S		Unk, Cyclic 21-Day Cycles, 4 Cycles		Pfizer
	Hydroxychloroquine			S		Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G		Not Reported
	Anastrozole			S		Unk Total Of 4 Months		Not Reported
	Cyclophosphamide			S		Unk, Cyclic 21-Day Cycles, 4 Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15032295	EXPEDITED (15-DAY)		OT	US-SA-2018SA149938		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Anastrozole			S				Not Reported
	Hydroxychloroquine			S		Daily Dose: 7.01 Mg/Kg		Sanofi
	Cyclophosphamide			S		21-Day Cycles		Not Reported
	Docetaxel			S		21-Day Cycles		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15335557	EXPEDITED (15-DAY)		HO, LT, OT	MX-PFIZER INC-2018348261		67 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Cardiac Failure Acute; Drug Interaction; Long Qt	Amiodarone Hcl			S	Oral	900 Mg, Daily (Every 24 Hours), Bolus Subsequent Dose		Pfizer

Syndrome; Presyncope; Sinus Bradycardia	Amiodarone Hcl		S	Unknown	200 Mg, 4x/Day	Pfizer
	Amiodarone Hcl		S	Intravenous (not otherwise specified)	300 Mg, Unk (Bolus)	Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]		S		200 Mg, Daily (Every 24 Hours)	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]		S	Unknown	200 Mg, 4x/Day	Not Reported
	Furosemide		S	Unknown	20 Mg, 4x/Day	Not Reported
	Warfarin Sodium		S	Unknown	2.5 Mg, 4x/Day	Not Reported
	Digoxin		C		Unk	Not Reported
	Digoxin		C			Not Reported
	Digoxin		C			Not Reported
	Spironolactone		C		Unk	Not Reported
	Spironolactone		C			Not Reported
	Spironolactone		C			Not Reported
	Metoprolol		C		Unk	Not Reported
	Metoprolol		C			Not Reported
	Metoprolol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15411121	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185070		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Perindopril			S	Oral	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported
	Repaglinide			S	Oral	()		Sun
	Plaquenil			S	Oral	200 Mg/Jour		Not Reported
	Cortancyl			S	Oral	10-20µg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16001840	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1017013		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Mobility Decreased; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S				Actavis
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Oral			Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate			S				Barr
	Naproxen			S	Unknown			Teva
	Naproxen			S				Teva
	Naproxen			S				Teva
	Naproxen			S				Teva
	Sulfamethoxazole And Trimethoprim			S	Unknown			Actavis
	Sulfamethoxazole And Trimethoprim			S				Actavis
	Sulfamethoxazole And Trimethoprim			S				Actavis
	Sulfamethoxazole And Trimethoprim			S				Actavis
	Ibuprofen			S	Unknown			Actavis
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Oral			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Enbrel	S		Not Reported
Enbrel	S		Not Reported
Enbrel	S		Not Reported
Gold Injections	S	Unknown	Not Reported
Gold Injections	S		Not Reported
Gold Injections	S		Not Reported
Gold Injections	S		Not Reported
Humira (Adalimumab)	S	Subcutaneous	Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Oral	Not Reported
Hydroxychloroquine Sulfate Tablets	S		Not Reported
Motrin	S	Unknown	Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Sodium Aurothiomalate Injection Bp	S	Parenteral	Not Reported
Sodium Aurothiomalate Injection Bp	S	Unknown	Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Vitamin C	S	Unknown	Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported

	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Voltaren	S	Unknown	Not Reported
	Acetylsalicylic Acid/Clopidogrel	S	Unknown	Not Reported
	Apo-Diclofenac	S	Unknown	Not Reported
	Apo-Sulfatrim	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16047193	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020789		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Celebrex			S	Oral	200milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported

	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16397631	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210010			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Infection Reactivation; Leishmaniasis; Sensation Of Foreign Body; Visceral Leishmaniasis; Visceral Leishmaniasis	Diclofenac			S	Unknown	Unk ()		Sun
	Hydroxychloroquine			S	Unknown	Unk ()		Sun
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16461090	EXPEDITED (15-DAY)		CA, DE, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-211015			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	20 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Enrobe			S	Transplacental	400 Milligram, Daily		Not Reported
	Diffu K, Gelule			S	Transplacental	1 Dosage Form, Daily		Not Reported
	Cortancyl 5 Mg, Comprime			S	Transplacental	1 Dosage Form, Daily		Not Reported
	Imurel			S	Transplacental	150 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16544910	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC-2019288608		29 YR	Female	USA

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

Off Label Use; Product Use In Unapproved Indication; West Nile Viral Infection	Methotrexate Sodium	S	Unk	Pfizer
	Methylprednisolone	S	Unk (High Dose)	Pfizer
	Rituximab	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported
	Prednisone	S	6 Mg, Daily (Tapering Of The Dose)	Not Reported
	Mycophenolate Mofetil	S	Unk	Not Reported
	Trimethoprim Sulfamethoxazole	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16576751	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-034879		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Acne; Appendicitis Perforated; Arthralgia; Asthenia; Bradycardia; Depressed Mood; Erythema; Fatigue; Gastrointestinal Disorder; Headache; Hypertension; Lethargy; Malaise; Nausea; Pain; Pain In Extremity; Peritonitis; Rash; Synovial Cyst	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Cipralex [Escitalopram]			C	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Colace			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17165875	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151435			Female	CAN

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

Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Methotrexate	S	Unknown			Barr
	Leflunomide	S	Unknown	400 Milligram Daily;		Barr
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17188130	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000131			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinal Dystrophy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Cellcept			C		Unk		Not Reported
	Arotinolol Hydrochloride			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Takecab			C		Unk		Not Reported
	Rivotril			C		Unk		Not Reported
	Bonoteo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17200794	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019232735			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline

Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	0.5 Milligram	Glaxosmithkline
	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Cimzia	S			Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S			Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	400 Mg, We, 400 Milligram, Weekly (Qw)	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported
	Simponi	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Subcutaneous	Solution	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S	Unknown	20 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Winpred	S	Oral	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported

Prednisone	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Etanercept	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram		Not Reported
Topicort Lp	S	Oral	Unk		Not Reported
Diclofenac	C	Unknown	50 Milligram, Once Daily (Qd)		Glaxosmithkline
Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)		Glaxosmithkline
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)		Not Reported
Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)		Not Reported
Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17425099	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2020023487		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anaemia; Dizziness; Haemolytic Uraemic Syndrome; Hypotension; Nausea; Product Dose Omission; Renal Injury; Urinary Tract Infection	Benlysta			S	Intravenous (not otherwise specified)	Unk Unk, We		Glaxosmithkline
	Cipro			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17623534	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340450		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Underdose; Vomiting	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naprosyn /00256201/			C	Unknown			Not Reported
	Naprosyn /00256201/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17666360	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009894		35 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis	Leflunomide		S	Unknown	20 Mg, Unk	Apotex
	Hydroxychloroquine		S	Unknown	400 Mg, Qd	Apotex
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	20 Mg, Qd	Not Reported
	Enbrel		S	Unknown	50 Mg, Q.Wk.	Not Reported
	Methotrexate		S	Oral	20 Mg, Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Simponi		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	300 Mg, Qd	Not Reported
	Xeljanz		C	Oral	5.0 Mg, Bid	Not Reported
	Magnesium		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Calcium		C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701054	EXPEDITED (15-DAY)		CA, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244979			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Paracetamol		Y	S	Transplacental	Unk ()		Ohm Lab
	Keppra			S	Transplacental	Unk ()		Not Reported
	Trileptal			S	Transplacental	Unk ()		Not Reported
	Plaquenil			S	Transplacental	Unk ()		Not Reported
	Kaleorid			C	Transplacental	Unk		Not Reported
	Orocal D3			C	Transplacental	Unk		Not Reported
	Speciafoldine			C	Transplacental	Unk ()		Not Reported
	Cortancyl			C	Transplacental	Unk ()		Not Reported

	Diffu-K		C	Transplacental	Unk ()	Not Reported
	Actonel		C	Transplacental	Unk ()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701285	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244571		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701299	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244572		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701322	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-019746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Rituximab	S	Intravenous drip	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701422	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020069		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Once A Day		Aurobindo
	Effexor			S	Oral	150 Milligram, Daily		Not Reported
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported
	Acebutolol			C	Oral	400 Milligram, Once A Day		Not Reported
	Amlodipine			C	Oral	10 Milligram, Once A Day		Not Reported
	Clomipramine Hydrochloride			C	Oral	150 Milligram, 1 Month		Not Reported
	Enoxaparin			C	Subcutaneous	4000 International Unit, Daily		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligram, Once A Day		Not Reported
	Macrogol 4000			C	Oral	2 Dosage Form, Daily		Not Reported
	Nicardipine Hydrochloride			C	Oral	60 Milligram, Daily		Not Reported
	Oxazepam			C	Oral	100 Milligram, Once A Day		Not Reported
	Zopiclone			C	Oral	7.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701432	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020070		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Once A Day		Aurobindo
	Loxapine			S	Oral	155 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Theralene			S	Oral	50 Milligram, Once A Day		Not Reported
	Akineton			C	Oral	4 Milligram		Not Reported
	Atorvastatine			C	Oral	40 Milligram, Once A Day		Not Reported

Diazepam	C	Oral	10 Milligram, Once A Day		Not Reported
Ezetimibe	C	Oral	10 Milligram, Once A Day		Not Reported
Kardegic	C	Oral	75 Milligram, Once A Day		Not Reported
Macrogol 4000	C	Oral	Unk		Not Reported
Nebivolol	C	Oral	7.5 Milligram, Once A Day		Not Reported
Nicopatch	C	Transdermal	7 Milligram, Once A Day		Not Reported
Nicotine	C	Oral	12 Milligram, Once A Day		Not Reported
Paracetamol	C	Oral	1 Gram, Once A Day		Not Reported
Ramipril	C	Oral	1.25 Milligram, Once A Day		Not Reported
Zopiclone	C	Oral	7.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702414	EXPEDITED (15-DAY)		HO, LT, OT	ES-SA-2020SA105860		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Metamizole Salt Not Specified			S	Intravenous (not otherwise specified)	2 G, Q8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702855	EXPEDITED (15-DAY)			CA-SA-2020SA102454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pregnancy	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	, 20-12.5 Mg;Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported

	Hydroxychloroquine			S	Unknown	300 Mg			Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702988	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226290		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Milligram Daily; Route Of Administration: Sng		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703170	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2020-01206			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Infection; Respiratory Tract Infection; Secondary Immunodeficiency; Urinary Tract Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Mycophenolate Mofetil			S				Alkem
	Azathioprine			S	Unknown	Unk		Alkem
	Azathioprine			S				Alkem
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703204	EXPEDITED (15-DAY)		OT	DE-HIKMA PHARMACEUTICALS USA INC.-DE-H14001-20-511		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes	Ceftriaxone			S	Unknown			Hikma

Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Ceftriaxone Sodium	S	Unknown		Not Reported
	Streptomycin	S	Unknown		Not Reported
	Prednisone	S	Unknown	()	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Cotrimoxazole	S	Unknown		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Doxycycline	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Acyclovir	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703265	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226288		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Drug Interaction; Tachyarrhythmia	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703315	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003552			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sjogren'S Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703409	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020223		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Aurobindo
	Plaquenil			S	Oral			Not Reported
	Zithromac			S	Oral	500 Milligram, Once A Day		Not Reported
	Zyvoxid			C	Intravenous (not otherwise specified)	1200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703414	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020196		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Amoxicillin+Clavulanic Acid			S	Oral	1 Comp/8h		Aurobindo
	Levofloxacin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Metronidazole			S	Oral	Unk		Aurobindo
	Dolquine			S	Oral	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703479	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3376441-00		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703559	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003551			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hypertension; Multiple Organ Dysfunction Syndrome; Off Label Use; Paralysis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703593	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003545			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant; Papilloma Viral Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703666	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226209		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Quetiapina (1136a)			S	Oral	25 Mg		Teva
	Levofloxacino (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Risperidona (7201a)			S	Oral	1 Mg		Actavis
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Losartan (7157a)			C	Oral	50 Mg		Not Reported
	Clindamicina Hidrocloruro (616ch)			C	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Lorazepam (1864a)			C	Oral	1 Mg		Not Reported
	Furosemida (1615a)			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703680	EXPEDITED (15-DAY)		OT	FI-ADVANZ PHARMA-E2B_00008842			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703729	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003540			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chemotherapy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703911	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004003504			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Disease Progression; Lymphopenia	Hydroxychloroquine			S	Oral	200 Mg, (Film Coated Tablet)		Concordia
	Repaglinide			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Glimepiride			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Perindopril			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Levocetirizine			C		Unk		Not Reported
	Finasteride			C		Unk		Not Reported
	Pregabaline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704031	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection	Hydroxychloroquine 400 Mg			S	Oral			Not Reported
	Hydroxychloroquine 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704205	EXPEDITED (15-DAY)		HO, OT	LT-ADVANZ PHARMA-GSH201609-004911			Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Body Temperature Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Enzyme Increased; Inflammatory Marker Increased; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704214	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003538			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Arava			S	Unknown	10 Mg		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

Xeljanz Xr	C	Unk	Not Reported
Xeljanz	C	Unk	Not Reported
Pregabalin	C	Unk	Not Reported
Vitamin B12 [Vitamin B12 Nos]	C	Unk	Not Reported
Salazopyrin	C	Unk	Not Reported
Codeine	C	Unk	Not Reported
Prednlsone	C	Unk	Not Reported
Synthroid	C	Unk	Not Reported
Cortisone	C	Unk	Not Reported
Dexilant	C	Unk	Not Reported
Vitamin D [Vitamin D Nos]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704217	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003541			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	1000 Mg, Bid		Concordia
	Orencia			S	Unknown	Unk		Not Reported
	Losec			C				Not Reported
	Clopidogrel			C		Unk		Not Reported
	Rosuvastatin			C				Not Reported
	Perindopril			C				Not Reported
	Nitrospray			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704377	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-01788		51 YR	Female	IND

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

Deafness Neurosensory; Ototoxicity	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Lupin
	Prednisolone	C	Unknown	40 Milligram, Qd	Not Reported
	Prednisolone	C	Unknown	5 Milligram, Qd (Gradually Tappered)	Not Reported
	Prednisolone	C	Unknown	10 Milligram, Qd (Dose Increased)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705063	NON-EXPEDITED			US-PFIZER INC-2020159965		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705271	EXPEDITED (15-DAY)		DE	ES-JNJFOC-20200419053		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Risperdal			S	Oral			Janssen
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Quetiapine			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Kaletra			S	Oral	200/50 Mg		Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemida /00032601/			C	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamicina /00166002/			C	Intravenous (not otherwise specified)			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705322	DIRECT		DE, HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Dysfunction; Cardio-Respiratory Arrest; Fall; Hallucination, Visual; Pulmonary Hypertension	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Triamcinolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705467	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100979		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Solution Subcutaneous		Not Reported
	Orencia			S	Subcutaneous	750 Mg		Not Reported
	Rituximab			S	Intravenous drip	2000 Mg		Not Reported
	Xeljanz			S				Not Reported
	Xeljanz			S	Oral	50 Mg, Bid (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705685	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2020162444		62 YR	Male	FRA

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

Off Label Use; Product Use In Unapproved Indication; Sudden Death	Zithromax		S	Oral	500 Mg, 1x/Day	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	600 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705686	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162461		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Other	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported
	Primperan			S	Intravenous drip	30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705727	EXPEDITED (15-DAY)		HO	CA-SAOL THERAPEUTICS-2020SAO00108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Rho D Immune Globulin			S				Saol Therapeutics
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, 1x/Month		Not Reported
	Arava			S		20 Mg		Not Reported
	Benzalkonium Chloride			S				Not Reported
	Benzalkonium Chloride/ Diphenhydramine Hydrochloride/ Phenylephrine Hy			S				Not Reported
	Boric Acid			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Disodium Edetate			S				Not Reported
	Enbrel			S	Subcutaneous	40 Mg, 1x/Week		Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported

Methotrexate	S	Oral	15 Mg, 1x/Week		Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phenylephrine Hydrochloride	S				Not Reported
Rituximab	S				Not Reported
Simponi	S				Not Reported
Sodium Borate	S				Not Reported
Sulfasalazine	S	Oral			Not Reported
Tofacitinib Citrate	S		10 Mg, 2x/Week		Not Reported
Tofacitinib Citrate	S		5 Mg, 2x/Week		Not Reported
Tofacitinib Citrate	S	Subcutaneous	5 Mg, 2x/Week		Not Reported
Celebrex	C	Oral	400 Mg		Not Reported
Ibuprofen	C	Oral	400 Mg		Not Reported
Lipitor	C	Oral	10 Mg, 1x/Day		Not Reported
Prednisone	C				Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705848	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3376750-00		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Ageusia; Anosmia; Condition Aggravated; Nausea; Off Label Use; Oxygen Saturation; Productive Cough; Pyrexia	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Heparin			C		Prophylactic Dose		Not Reported
	Tocilizumab			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705929	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1226300		70 YR	Male	FRA

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

Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycine Anhydre	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Lovenox	C	Oral	Not Reported
	Paracetamol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705944	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226289		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1 Gram Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706122	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032305			Female	CAN

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

Cetirizine Hydrochloride	S	Unknown	Unk		Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Cortisone Acetate	S	Unknown	Unk		Not Reported
Cortisone Acetate	S	Unknown			Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Folic Acid	S	Unknown	5 Milligram		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706431	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226597		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Tofacitinib Citrate	S	Oral	10 Milligram Daily;		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
Aspirin [Acetylsalicylic Acid]	C	Unknown			Not Reported
Cimzia Single-Use Prefilled Syringe	C	Subcutaneous			Not Reported
Cymbalta	C	Unknown			Not Reported
Hydromorphone	C	Unknown			Not Reported
Remicade	C	Intravenous (not otherwise specified)			Not Reported
Synthroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706432	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226715			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706435	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226417		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706545	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported

	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706575	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226588		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate			S	Oral			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown	100 Milligram Daily;		Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Vitamin D3	C				Not Reported
	Imuran [Azathioprine]	C				Not Reported
	Gold	C				Not Reported
	Arthrotec	C	Unknown	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706582	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226586		59 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706588	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226758		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706589	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1226786			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Off Label Use; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706590	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226708		65 YR	Female	CAN

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

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706609	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226204		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706659	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226499			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered	Leflunomide			S	Unknown			Barr

	Methotrexate			S	Unknown				Barr
	Prednisone			S	Unknown				Actavis
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Arava			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Actemra			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706688	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole			C	Oral	40 Milligram Daily;		Not Reported

Tenofovir Disoproxil	C	Unknown			Not Reported
Tenofovir Disoproxil	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Zopiclone	C	Unknown	7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706692	EXPEDITED (15-DAY)		OT	NVSC2020DE069507		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Ramipril			S	Oral	Unk		Not Reported
	Amlodipine			S	Unknown	Unk		Novartis
	Esomeprazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Boswellia Serrata Extract			S	Unknown	Unk		Not Reported
	Thyroxine			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706698	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226415		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Aspirin [Acetylsalicylic Acid]	C			Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706706	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706708	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706711	EXPEDITED (15-DAY)		DE, LT	NVSC2020CA108434		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Orencia	S				Not Reported
Oxycodone	S	Unknown	10 Mg		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S				Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Sodium Aurothiomalate	S				Not Reported
Xeljanz	S	Oral	2 Df, Qd		Not Reported
Leflunomida	S	Unknown			Not Reported
Minocycline Hydrochloride	S	Unknown			Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Kineret	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706712	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226575		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	20 Milligram Daily;		Not Reported
	Orencia			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

	Remicade	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706716	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706718	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226485		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706719	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C				Not Reported
	Tylenol W/Codeine No.3			C				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706723	EXPEDITED (15-DAY)		LT	NVSC2020CA108426		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Oxycodone			S	Unknown	10.0 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported

Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hidroxicloroquina	S	Unknown		Not Reported
	Hidroxicloroquina	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	Unk (2 Every 1 Days)	Not Reported
	Kineret	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706744	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226225			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706821	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226617		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Unknown	12.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	20 Mg, 4 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

	Rituxan		C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226496		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tylenol			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

Synthroid	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706884	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226629		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706888	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226486		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Aspirin[Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706960	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706962	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Abnormal; Synovitis	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid		C	Unknown		Not Reported
	Hydroxychloroquine Sulfate		C	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706969	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226569			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706970	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226578		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Leflunomide			S	Unknown			Barr

Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate		S	Unknown		Barr
	Methotrexate		S	Unknown		Barr
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Oral		Barr
	Methotrexate		S	Subcutaneous		Barr
	Alendronate		S	Unknown		Actavis
	Codeine		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Myochrysine		S	Intramuscular		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous drip	2000 Milligram Daily;	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Ciclosporin		C			Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707004	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226718		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Alendronic Acid	S	Unknown		Actavis
	Codeine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707009	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226580			Female	CAN

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

Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Bifidobacterium Bifidum	C	Unknown		Not Reported
	Loperamide	C	Oral		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226576			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707742	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226778		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707753	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1225340			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Cyclobenzaprine Hcl 5 Mg Tablet			S	Unknown			Actavis
	Xeljanz			S	Oral	10 Milligram Daily; 60/Btl		Not Reported
	Narcan 4 Mg Spray			S	Unknown	Spray		Not Reported
	Plaquenil 200 Mg Tablet			S	Unknown			Not Reported
	Hydrochlorothiazide 25 Mg Tablets			S	Unknown			Not Reported

	Wellbutrin Xl Tab Er	S	Unknown	150 Milligram Daily; Er	Not Reported
	Wellbutrin Xl Tab Er	S	Unknown	300 Milligram Daily; Er	Not Reported
	Prednisone 10 Mg Tablet	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707828	EXPEDITED (15-DAY)		HO	ES-009507513-2004ESP006461		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Ertapenem Sodium			S	Intravenous (not otherwise specified)	1 G Day		Merck
	Piperacillin Sodium (+) Tazobactam Sodium			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Azithromycin			S	Oral	500 Mg Per Day		Not Reported
	Dolquine			S	Oral	400 Mg Per Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707836	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707886	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226781		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive	Leflunomide			S	Unknown			Barr

Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Naproxen Sodium		S	Unknown		Teva
	Prednisone		S	Unknown		Actavis
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid		C	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17710887	DIRECT		DE			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Myocardial Infarction	Hydroxychloroquine	Y		S				Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	14994173	EXPEDITED (15-DAY)		OT	US-ACCORD-067914		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Visual Field Defect	Anastrozole			S				Accord
	Docetaxel			S		Four 21-Day Cycles		Not Reported
	Hydroxychloroquine			S		Hcq Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S		21-Day Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	15611218	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-091251		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Intolerance; Gastrointestinal Disorder; Haematuria; Headache; Hypertransaminasaemia; Nausea; Pneumonia; Proteinuria; Pyrexia; Respiratory Symptom	Mycophenolic Acid			S				Accord
	Tacrolimus			S				Accord
	Hydroxychloroquine			S				Not Reported
	Rituximab			C				Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			C		Pulse		Not Reported
	Methylprednisolone			C				Not Reported
	Amphotericin B/Amphotericin B/Liposome			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	16739695	EXPEDITED (15-DAY)		OT	DE-ACCORD-152822			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df Bid (1-0-1), 2x/Day		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1-1-1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown			Not Reported
	Ambrisentan			S				Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg Bid		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1-0-1), 5 Mg Per Day, 2.5 Mg Bid,		Not Reported
	Roactemra			S		162 Mg, Qw		Not Reported
	Spasmolyt			S		15 Mg, Qd (1-0-0),Also Received 30 Mg (0 -0 -1)		Not Reported
	Omeprazole			S	Oral	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg, Bid		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Spasmolyt			S		30 Mg (0 -0 -1)		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported

	Ramipril	S	Unknown		Accord
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
	Volibris	S	Oral		Not Reported
	Trospium Chloride	S		30 Mg (0 -0 -1)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17678870	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002849			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Coma; Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	Unk		Concordia
	Midazolam			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Morphine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17707971	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003553			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Eye Disorder; Off Label Use; Product Dose Omission	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708013	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-GSH201610-005089			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Dilatation Atrial	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Methotrexate			S	Unknown	7.5 Mg Every 10 Days		Not Reported
	Methotrexate			S		Reduction In The Dose Of Methotrexate 7.5 Mg		Not Reported

					Every 10 Days	
	Certolizumab Pegol		S	Unknown	200 Mg Every Other Week	Not Reported
	Certolizumab Pegol		S	Unknown	200 Mg Every Other Week	Not Reported
	Bromazepam		C			Not Reported
	Bromazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708019	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-MAPI_00011385			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Function Test Abnormal; Cardiotoxicity; Ejection Fraction Decreased; Product Use In Unapproved Indication; Sinus Tachycardia; Tachycardia; Ventricular Hypokinesia	Hydroxychloroquine			S	Unknown	600 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Doxycycline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708183	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004004057			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708184	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004003665			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17574299	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201806-002062			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	7.01 Mg/Kg, Qd (Total Cumulative Dose 402 G)		Concordia
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported
	Docetaxel			S	Unknown	21-Day Cycles		Not Reported
	Anastrozole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708342	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA108440			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Thrombosis; Urticaria	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported

Arava	S				Not Reported
Enbrel	S	Subcutaneous			Not Reported
Enbrel	S				Not Reported
Gold	S	Unknown			Not Reported
Gold	S				Not Reported
Humira	S	Subcutaneous			Not Reported
Humira	S				Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S				Not Reported
Marijuana	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S				Not Reported
Oxycodone	S	Unknown	10 Mg		Not Reported
Plaquenil	S	Oral			Not Reported
Plaquenil	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S				Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Sodium Aurothiomalate	S				Not Reported
Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708442	EXPEDITED (15-DAY)		OT	NVSC2020CA111350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Hypothyroidism; Obesity; Osteoarthritis; Osteopenia; Synovitis; Therapeutic Product Effect Incomplete	Cosentyx			S	Unknown	Unk Unk, Unknown		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	N-(3-Chloroallyl)Hexaminium			S	Unknown	Unk		Not Reported

Chloride					
Penicillin G	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	50 Mg, Qmo		Not Reported
Stelera	S	Unknown	Unk, 1 Every 8 Weeks		Not Reported
Stelera	S	Subcutaneous	Unk		Not Reported
Cetirizine	C	Unknown	10 Mg, Bid		Not Reported
Enbrel	C	Unknown	50 Mg, Qw		Not Reported
Lasix	C	Unknown	40 Mg, Qmo		Not Reported
Montelukast	C	Unknown	10 Mg, Qd		Not Reported
Synthroid	C	Unknown	75 Mg, Qd		Not Reported
Terbutaline Sulfate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708667	EXPEDITED (15-DAY)		OT	NVSC2020CH106927		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Product Use In Unapproved Indication; Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Methotrexate			S	Unknown	Unk Ukn		Not Reported
	Azathioprine			S	Unknown	Unk Ukn		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Ukn		Not Reported
	Infliximab			S	Unknown	Unk Ukn		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17709300	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2020-020616			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

	Plaquenil	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17711723	DIRECT					28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Hydroxychloroquine	Y		S	Oral			Not Reported
	Propranolol			C				Not Reported
	Valium			C				Not Reported
	Prilosec			C				Not Reported
	Pristiq			C				Not Reported
	Norethidrone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15208961	EXPEDITED (15-DAY)		HO, OT	GR-ALLERGAN-1835963US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Raynaud'S Phenomenon; Renal Impairment; Scleroderma; Scleroderma Renal Crisis; Thrombocytopenia; Weight Decreased	Citalopram Hydrobromide Unk			S	Unknown	Unk		Allergan
	Alprazolam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q Week		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Folate			S	Unknown	5 Mg, Q Week		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Captopril			S	Unknown	Unk		Not Reported
	Captopril			S				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15567436	NON-EXPEDITED			US-PFIZER INC-2018432992		74 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16646824	EXPEDITED (15-DAY)		HO, OT	PL-PFIZER INC-2019317440		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Sulfasalazine			S	Unknown	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	15 Mg, Qd (Every Day)		Not Reported
	Encorton			S	Unknown	10 Mg, Qd (Every Day)		Not Reported
	Plaquenil S			S		20 Mg, 1x/Day; Qd		Not Reported
	Erelzi [Etanercept]			S	Intravenous (not otherwise specified)	50 Mg, Unk		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Metex [Methotrexate Sodium]			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16783255	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001712			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Hydroxychloroquine			S	Oral	400 Mg, Qd Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S		Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk Subcutaneous Solution		Not Reported
	Humira			S	Subcutaneous	40 Mg; Subcutaneous Solution		Not Reported
	Levofloxacin Hemihydrate			S	Unknown	Unk		Not Reported
	Levofloxacin Hemihydrate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported

Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	1 Dosage Form, Weekly	Not Reported
Metronidazole	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
Metronidazole	S			Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Cefaclor	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Celecoxib	S	Oral	200 Mg	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Apo-Bisoprolol	S	Unknown	Unk	Not Reported
Meperidine	S	Unknown	Unk	Not Reported
Levofloxacin	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Erythromycin Estolate	S	Unknown	Unk	Not Reported
Erythro Base	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	400 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16944449	EXPEDITED (15-DAY)		HO	US-EMCURE PHARMACEUTICALS LTD-2018-EPL-0469		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypokalaemia; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram		Emcure
	Hydroxychloroquine			S		4 Dosage Form		Not Reported
	Activated Charcoal			C	Oral	50 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17182234	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1154329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Blood Test Abnormal; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Otezla			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Doxepin Hydrochloride			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17298077	EXPEDITED (15-DAY)		OT	FR-ACCORD-168315		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis	Mycophenolic Acid			S	Unknown			Accord

	Hydroxychloroquine	S	Unknown		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Belimumab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17584892	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020125649		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17647567	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17659064	EXPEDITED (15-DAY)		DE, OT	TH-ROCHE-2577353		44 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cerebral	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg/Day		Not Reported

Haemorrhage; Injection Site Extravasation; Intentional Product Use Issue; Off Label Use; Proteinuria; Renal Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Lopinavir	S	Unknown	Not Reported
	Ritonavir	S	Unknown	Not Reported
	Favipiravir	S	Unknown	Not Reported
	Darunavir	S	Unknown	Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	Not Reported
	Piperacillin	S	Unknown	Not Reported
	Tazobactam	S	Unknown	Not Reported
	Vancomycin	S	Unknown	Not Reported
	Enoxaparin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17666598	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201712-006550			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Celebrex			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672025	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413067		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Simponi			S	Subcutaneous			Janssen

Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672031	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072603/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17679287	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Responder	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	716.25 Mg, Unk	Not Reported
	Aspirin /00002701/	C	Unknown	Unk	Not Reported
	Clopidogrel Bisulfate	C	Oral	Unk	Not Reported
	Ezetrol	C	Oral	Unk	Not Reported
	Niaspan Er	C	Unknown	Unk	Not Reported
	Nitroglycerin	C	Transdermal	Unk	Not Reported
	Rosuvastatin Calcium	C	Oral	Unk	Not Reported
	Tylenol /00020001/	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17687090	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003003347			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17702991	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226210		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Propofol Infusion Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Propofol 2% Inyectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

	Dexametasona (722a)	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709439	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226654		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			C				Not Reported
	Azitromicina (7019a)			C	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709444	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Left Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Tofacitinib			C		Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Infliximab			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709445	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003658			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonitis; Product Availability Issue	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709452	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245108		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Pantoprazol			S	Intravenous (not otherwise specified)	Unk		Sun
	Tacrolimus Monohydrate			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Pentasa			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709467	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245124		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported
	Ceftriaxone Base			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto 10 Mg, Comprime Pellicule			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709667	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226969		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Thrombocytopenia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709805	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709830	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002639			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Treatment Noncompliance	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709947	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226986		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily; Every 8 Hours		Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710025	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226989		52 YR	Female	ESP

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

Condition Aggravated; Hepatitis Cholestatic	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;	Not Reported
	Ceftriaxona (501a)	S			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710046	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226987		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 120 Tablets		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710318	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588918		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710626	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226932		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Parenteral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710627	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226939		70 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710635	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226954		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Arava	C				Not Reported
	Naproxen	C	Unknown	1000 Milligram Daily;		Not Reported
	Viread	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710680	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226998		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710682	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226993		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C				Not Reported
	Arava			C				Not Reported
	Benadryl			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Viread			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710749	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1040162			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios;	Omeprazole			S		Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Metoprolol			S	Transplacental	Unk		Not Reported

Premature Baby	Dexamethasone	S	Transplacental	Unk	Mylan
	Dexamethasone	S	Transplacental	Unk	Mylan
	Albumin	S	Transplacental	Unk	Mylan
	Penicillin-G	S	Transplacental	Unk	Mylan
	Prednisone	S	Transplacental	Unk	Mylan
	Prednisone	S	Transplacental	Unk	Mylan
	Vitamin D /00318501/	S	Transplacental	Unk	Mylan
	Hydroxychloroquine	S		Unk	Mylan
	Vitamin B Complex /00003501/	S	Unknown	Unk	Mylan
	Paracetamol	S	Transplacental	Unk	Mylan
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Mylan
	Flebogamma Dif /00025201/	S	Transplacental	Unk	Mylan
	Magnesium Lactate	S	Transplacental	Unk	Mylan
	Bisoprolol Fumarate	S	Transplacental	Unk	Mylan
	Privigen	S	Transplacental	Unk	Mylan
	Privigen	S	Transplacental	Unk	Mylan
	Fluconazole	S	Transplacental	Unk	Mylan
	Hydrocortisone	S	Transplacental	Unk	Mylan
	Vulmizolin	S	Transplacental	Unk	Mylan
	Cefotaxime	S	Transplacental	Unk	Mylan
	Cefotaxime	S	Transplacental	Unk	Mylan
	Potassium Chloride	S	Transplacental	Unk	Mylan
	Folic Acid	S	Transplacental	Unk	Mylan
	Bisulepin	S	Transplacental	Unk	Mylan
	Etamsylate	S	Transplacental	Unk	Mylan
	Nadroparine	S	Transplacental	Unk	Mylan
	Ornidazole	S	Transplacental	Unk	Mylan
	Methylprednisolone	S	Transplacental	Unk	Mylan
	Methylprednisolone	S	Transplacental	Unk	Mylan

	Cefixime	S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710751	NON-EXPEDITED			US-PFIZER INC-2020165061		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711227	NON-EXPEDITED			US-PFIZER INC-2020167983		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Hypersensitivity; Dyspnoea; Nausea; Swelling; Vomiting; Wheezing	Gabapentin			S		Unk		Pfizer
	Baclofen			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Linzess			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711246	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227339		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities;	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226940		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711308	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226958		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Indometacin			S	Unknown			Not Reported
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Cymbalta		C	Oral	30 Milligram Daily;	Not Reported
	Folic Acid		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711319	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226935		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	12 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	12.5 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Unknown	10 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	17.5 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	10 Mg, 1 Every 1 Week		Barr
	Alendronic Acid			S	Unknown	70 Mg, 1 Every 1 Week		Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711477	EXPEDITED (15-DAY)		OT	NVSC2020FR109492		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Eruption; Pyrexia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			C	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711543	EXPEDITED (15-DAY)		DE, OT	ES-ASTELLAS-2020US014740		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711604	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226653		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 200 Mg/12h		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 2 Comp/12h		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711810	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2020167297		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711951	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226990		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr

	Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712080	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226652		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg/24h		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Single Dose		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712129	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226773		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712238	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712368	EXPEDITED (15-DAY)		OT	NVSC2020CA111106		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Retinal Toxicity	Hydroxychloroquine			S	Unknown	5.3 Mg/Kg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	2.7 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712393	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226967		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712394	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226772		30 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

	Hidroxicloroquina (2143a)	S				Teva
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712720	EXPEDITED (15-DAY)		HO, OT	SE-PFIZER INC-2020167060		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Df		Pfizer
	Sertraline Hcl			S	Oral	750 Mg		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	10-15 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17713099	DIRECT	Y	LT, OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17714446	EXPEDITED (15-DAY)		OT	NVSC2020CA111134		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	7.1 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715382	EXPEDITED (15-DAY)		HO	NVSC2020FR109498		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Product Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

In Unapproved Indication;
Pyrexia; Rash Pustular;
Skin Plaque

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715582	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2020DEP000202		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Assertio Therapeutics
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednison			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

Plaquenil /00072602/	S	Unknown	400 Mg, Qd		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Salazopyrine	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Sulfathalidine	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715715	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020561		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Rocephine			S	Oral	2 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715746	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-020590			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715772	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020598			Female	CAN

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

Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Meloxicam		S	Unknown	Unk	Aurobindo
	Arava		S	Unknown	Unk	Not Reported
	Belimumab		S	Unknown	Unk	Not Reported
	Breo Ellipta		S		Unk	Not Reported
	Celebrex		S	Unknown	Unk	Not Reported
	Colchicine		S	Unknown	Unk	Not Reported
	Dexilant		S	Oral	60 Milligram, Once A Day	Not Reported
	Estrogel		S	Topical	Unk, Once A Day	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Methotrexate		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil		S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Prednisone		S	Unknown	50 Milligram	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Ventolin Hfa		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715790	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226775		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715834	EXPEDITED (15-DAY)		HO	SE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245240		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram, Unk		Sun
	Prednisolone			S	Oral	10-15st.		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	15935909	EXPEDITED (15-DAY)		DE, OT	IT-ACCORD-104696		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Hydrochlorothiazide			S		Unk		Not Reported
	Lorazepam			S		Unk, Also Received As Concomitant.		Accord
	Montelukast			S		Unk, Also Received As Concomitant.		Not Reported
	Acetylsalicylic Acid			S		Unk, Also Received As Concomitant		Not Reported
	Celecoxib			S		Unk, Also Received As Concomitant.		Not Reported
	Hydroxychloroquine			S		Unk, Also Received As Concomitant.		Not Reported
	Influenza Vaccine			S		Unk		Not Reported
	Warfarin			S		Regimen 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16081389	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013165		56 YR	Female	CAN

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate Tablet	S	Unknown	35 Milligram, Every Week	Aurobindo
	Risedronate Tablet	S	Oral	35 Milligram, Every Week	Aurobindo
	Actemra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Form, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram, Every Week	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical (1 Every 1 Day)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk,Once A Day	Not Reported
	Actonel	S	Unknown	35 Milligram, Every Week	Not Reported
	Hydroxychloroquine	S	Unknown	Unk,Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Anakinra	S	Subcutaneous	100.0 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not	Unk	Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous	Unk		Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Two Times A Day		Not Reported
	Risedronate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16782017	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000468			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Meperidine Hydrochloride			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Tablet		Not Reported
	Methotrexate			S	Oral	1 Df, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Erythromycin Estolate			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported

	Arthrotec	S	Unknown	Unk	Not Reported
	Plaquenil /00072603/	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	400 Mg, Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16879886	EXPEDITED (15-DAY)		OT	GR-ACCORD-156263		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Accord
	Levothyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Dicoumarol			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17299448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527600		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17351623	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported

Norfloxacin	S	Unknown	400 Mg, Unk	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
Cefaclor	S	Unknown	Unk	Not Reported
Celecoxib	S	Oral	200 Mg, Unk	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Erythromycin Estolate	S	Unknown	Unk	Not Reported
Levofloxacin	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Plaquenil /00072603/	S	Oral	400 Mg, Qd	Not Reported
Plaquenil /00072603/	S	Oral	Unk	Not Reported
Arthrotec	S	Unknown	Unk	Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17426809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551542			Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17605318	EXPEDITED (15-DAY)		OT	AU-SA-2020SA072232		34 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Adrenal Haemorrhage; Atrial Septal Defect; Cerebral Infarction; Deep Vein Thrombosis; Myocardial Hypoperfusion; Myocarditis; Pulmonary Embolism; Pulmonary Infarction; Thrombotic Microangiopathy; Transient Ischaemic Attack	Enoxaparin Sodium			S		200 Mg		Sanofi
	Acetylsalicylic Acid			S		100 Mg		Not Reported
	Hydroxychloroquine			S		200 Mg		Sanofi
	Cyclophosphamide Monohydrate			C	Intravenous (not otherwise specified)	1.5 G		Not Reported
	Heparin Sodium			C				Not Reported
	Rituximab			C		1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17664343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Treatment	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Failure; Vomiting	Enbrel	S	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17678663	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224966		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	Unit Dose : 200 Mg 400mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17691116	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1225788		62 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatitis; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17693985	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic	Simponi			S	Subcutaneous			Janssen

Arthropathy; Synovitis	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17715963	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020588			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589484			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Bupropion	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716326	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227005		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716375	EXPEDITED (15-DAY)		HO	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-049454			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Simplex Hepatitis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Zydus Pharm

	Prednisone		S	Unknown	5 Milligram, Qd	Not Reported
	Prednisone		S	Oral	Unk	Not Reported
	Metronidazole		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229781		37 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716653	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Celebrex			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716681	EXPEDITED (15-DAY)		HO, OT	RO-ACCORD-136273		56 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Nodule	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Insulin			C		40 Ui		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716778	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1225767		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Unresponsive To Stimuli; Ventricular Fibrillation	Azithromycin			S	Oral	On Day 1		Not Reported
	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	800 Milligram Daily; On Day 1		Teva
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716808	EXPEDITED (15-DAY)		HO	ES-CIPLA LTD.-2020ES03040			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Milligram, Per Day		Cipla
	Dolquine			S	Oral	400 Milligram, Per Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Bid (Every 12 Hours; 2u/12 H)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716812	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589371			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Etanercept	S	Subcutaneous	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milliliter, Qd		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717266	EXPEDITED (15-DAY)		DE, OT	CA-ROCHE-2588343		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Death; Drug Ineffective; Drug Intolerance; Feeling Jittery; Joint Swelling; Limb Discomfort; Localised Infection; Malaise; Musculoskeletal Disorder; Nausea; Neck Pain; Night Sweats; Pain;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 128.0 Days		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Peripheral Swelling; Purulent Discharge; Pustular Psoriasis; Synovitis; Tachycardia; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 176.0 Days	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	Therapy Duration:4 Months	Not Reported
	Xeljanz	S	Oral	Therapy Duration:6 Months	Not Reported
	Acetylsalicylic Acid	S	Unknown		Not Reported
	Calcium	C	Oral		Not Reported
	Celebrex	C	Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
	Ergocalciferol	C	Oral		Not Reported
	Leucovorin Calcium	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Magnesium	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Valtrex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717567	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2020-IN-001291			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ototoxicity; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Prednisolone			C	Unknown	40 Milligram, Qd		Not Reported

	Prednisolone		C	Unknown	5 Milligram, Qd	Not Reported
	Prednisolone		C	Unknown	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588809		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718400	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Epistaxis; Headache; Insomnia; Joint Swelling; Nausea; Rash; Transaminases Increased; Vasculitis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Azathioprine			S	Oral	200 Milligram Daily;		Not Reported
	Azathioprine			S	Oral	50 Milligram Daily;		Not Reported
	Azathioprine			S	Oral	150 Milligram Daily;		Not Reported
	Mycophenolate Mofetil			S	Oral	2 Gram Daily;		Teva
	Mycophenolate Mofetil			S	Oral	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Imuran			S	Oral	50 Milligram Daily;		Not Reported
	Imuran			S	Oral	150 Milligram Daily;		Not Reported

Imuran	S	Oral	200 Milligram Daily;		Not Reported
Arava	S	Oral	20 Milligram Daily;		Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram Daily;		Not Reported
Methotrexate	S	Oral			Not Reported
Ketoprofen	C				Not Reported
Prednisone	C				Not Reported
Prolia Pre-Filled Syringe. Preservative-Free	C	Subcutaneous			Not Reported
Quetiapine	C	Oral	25 Milligram Daily;		Not Reported
Rituximab	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588638			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718533	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588767		56 YR	Female	CAN

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

Interstitial Lung Disease	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Methotrexate		S	Intramuscular	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Naprosyn [Naproxen]		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718649	EXPEDITED (15-DAY)		HO, LT	ES-ABBVIE-20K-144-3380621-00		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Kaletra 200/50			S	Oral			Not Reported
	Metilprednisolona			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588479			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Loss Of Consciousness; Vomiting	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam		C		Not Reported
	Sulfasalazine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718922	EXPEDITED (15-DAY)		DS	CA-ROCHE-2588501		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy	Actemra			S	Intravenous (not otherwise specified)	7.0 Years		Not Reported
	Rituxan			S	Intravenous drip	579.0		Not Reported
	Enbrel			S	Subcutaneous	9 Months		Not Reported
	Humira			S	Subcutaneous	7 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	2 Years		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)	2 Years		Not Reported
	Xeljanz			S	Unknown	2 Years		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17719461	EXPEDITED (15-DAY)		OT	NVSC2020SE113735		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S	Unknown	"Nov 2016 Höjdes Mtx Till 8 Tab/V".		Novartis
	Methotrexate			S	Unknown	6 Tabletter		Novartis
	Methotrexate			S	Unknown	7 Tabletter		Novartis
	Methotrexate			S	Unknown	"6 Tab. Methotrexat/V +5 Mg Prednisolon Under Många År".		Novartis
	Plaquenil			S	Unknown			Not Reported
	Prednisolone			C	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720803	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3378772-00		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Lopinavir/Ritonavir			S	Oral			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720916	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020972		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram (1 Total)		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

	Hydroxychloroquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720923	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020973		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Metamizol			S	Intravenous (not otherwise specified)	2 Gram, Four Times/Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720925	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020974		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17721027	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL		73 YR	Male	ESP

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun
	Hidroxicloroquina (2143a)			S	Oral	200 Mg/24h		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg/24h		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17722744	DIRECT	Y	DE			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive; Emergency Care	Hydroxychloroquine			S	Oral			Actavis
	Kaletra			S	Oral			Abbvie

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	12489538	EXPEDITED (15-DAY)		OT	CA-009507513-1606CAN007831		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Remeron			S	Oral	15 Mg		Merck
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Dosage Form Not Specified		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Methotrexate	S	Oral	25 Mg, Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Dosage Form Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13165249	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886155		67 YR	Female	CAN

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

Furosemide	C			Not Reported
Hydrochlorothiazide	C			Not Reported
Nifedipine	C			Not Reported
Palafer	C			Not Reported
Pantoprazole	C			Not Reported
Prednisone	C			Not Reported
Synthroid	C			Not Reported
Toloxin [Digoxin]	C			Not Reported
Valsartan	C			Not Reported
Vitamin D3	C	Unknown		Not Reported
Xarelto	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Zinc Citrate	C			Not Reported
Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13250722	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894453		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown	Cyclical		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Therapy Duration: 2 Years		Not Reported

				otherwise specified)	Cyclical		
	Sulfasalazine		S	Unknown			Not Reported
	Methotrexate		S	Unknown			Not Reported
	Apo-Azathioprine		S	Unknown			Not Reported
	Cyclosporine		S	Unknown			Not Reported
	Apo-Hydroxyquine		S	Unknown			Not Reported
	Gold		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15096452	EXPEDITED (15-DAY)		CA, DE, DS, OT	PHHY2018DE028935			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe			S	Transplacental	Unk		Novartis
	Ramipril			S	Transplacental	20 Mg, Unk (Maternal Dose)		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Metamizole			S	Transplacental	Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Rivaroxaban			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Mg, Qd		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Aliskiren			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Not Reported
	Torem			S	Transplacental	100 Mg, Qd		Not Reported
	Rasilez			S	Transplacental	300mg/D Unk		Not Reported
	Rasilez			S	Transplacental	100 Mg/D Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Nicotine			S	Transplacental	Unk		Not Reported

Mifegyne	C	Unknown	Unk		Not Reported
Cytotec	C	Unknown	Unk		Not Reported
Cyclophosphamide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15102944	EXPEDITED (15-DAY)		OT	PHHY2018DE028933		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Novartis
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Ramipril			S	Unknown	20 Mg, Unk		Not Reported
	Torasemide			S	Unknown	0-14 Gw		Not Reported
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Metamizole			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown	0-14 Gw		Not Reported
	Rivaroxaban			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Hydroxychloroquine			S	Unknown	0-14 Gw		Not Reported
	Prednisolone			S	Unknown	0-14 Gw		Not Reported
	Acetylsalicylic Acid			S	Unknown	0-14 Gw		Not Reported
	Pantoprazole			S	Unknown	0-14 Gw		Not Reported
	Nicotine			S	Unknown			Not Reported
	Enoxaparin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15416072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187971		57 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15593099	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018445495		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Aphthous Ulcer; Blood Cholesterol Increased; Constipation; Diarrhoea; Headache; Oral Candidiasis; Sinusitis	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S		11 Mg, Unk		Pfizer

	Plaquenil [Hydroxychloroquine Sulfate]	S	200 Mg, 2x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Cymbalta	C	Unk	Not Reported
	Clonazepam	C	Unk	Not Reported
	Hydroxychloroquine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15964988	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-ACCORD-107431			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril			S	Transplacental	20 Mg Per Day, Exposure Duration: 0-13+6 Weeks		Accord
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Accord
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Accord
	Ezetimibe			S	Transplacental	Also Received As Suspect, From Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental	40 Mg/D, 0-13.6 Gestational Week		Not Reported
	Salbutamol			S	Transplacental	From Gestational Week 0-14		Not Reported
	Metamizole Sodium			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Dalteparin			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Aliskiren			S	Transplacental	300 Mg/D, 0-4.6 Gestational Week		Not Reported

Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid Sandoz	S	Transplacental		Not Reported
Rivaroxaban	S	Transplacental		Not Reported
Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Unk, Trimester: First, Probably Only In Hospital In Week 5	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Cytotec	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Cyclophosphamide/Cyclophosphamide Monohydrate	C	Transplacental	3000 Mg Cumulative, Preconceptional	Not Reported
Enoxaparin	C	Transplacental	Unk Unk, Unknown Freq. (0-14 Gw), Also Received As Concomitant.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16080946	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013597		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-	Rosuvastatin Tablet			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Gold	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day		Not Reported
	Methotrexate	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16478155	EXPEDITED (15-DAY)		CA, DE, HO, OT	FR-ACCORD-135124			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental	Strength: 200 Mg, 1 Dosage Form, Once Daily (Qd)		Not Reported
	Diffu K			S	Transplacental	1 Dosage Form, Once Daily (Qd)		Not Reported
	Cortancyl			S	Transplacental	Strength: 5 Mg, 1 Dosage Form, Once Daily (Qd)		Not Reported
	Imurel			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16710864	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000394			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Meperidine /00016301/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16719064	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217711		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Qw		Not Reported

Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Celebrex		C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16880699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17259008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516331		43 YR	Female	CAN

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

	Xeljanz	C	Oral	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17339418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530858		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Injectable Suspension	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17401839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542463		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17583318	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001754			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Erythema; Inflammation; Pneumonia; Purulence; Pyrexia; Tenderness	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17669289	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010048		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Certolizumab Pegol			S	Subcutaneous	400 Mg, (Cyclical)		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17678101	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002848			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17682573	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202003002315			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Death; Off Label Use; Pulmonary Embolism	Hydroxychloroquine			S	Oral	800 Mg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Paracetamol			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Macrogol 3350			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Voriconazole			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17705879	EXPEDITED (15-DAY)		HO	CH-ABBVIE-20K-151-3376752-00		70 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral	800/200 Mg		Not Reported
	Kaletra			S	Oral	400/100 Mg		Not Reported
	Plaquenil			S	Oral	Initial Dose		Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			C	Intravenous drip			Not Reported

Co-Amoxi	C		Not Reported
Triatec [Ramipril]	C		Not Reported
Metfin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17716184	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3380425-00		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Piperacillina Sodica/Tazobactam Sodico			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229703			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588833		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Oral			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721370	EXPEDITED (15-DAY)		OT	ES-ADVANZ PHARMA-GSH201807-002384			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Congestive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721385	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589389		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588807		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721388	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-GSH201907-001665			Unknown	USA

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

Chills; Depressed Level Of Consciousness; Diarrhoea; Fatigue; Headache; Lethargy; Malaise; Mental Status Changes; Muscular Weakness; Myalgia; Nausea; Pyrexia; Tachycardia; Unresponsive To Stimuli; West Nile Viral Infection	Hydroxychloroquine	S	Unknown	Unk		Concordia
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S				Not Reported
	Prednisone	S	Unknown	6 Mg, Qd (Part Of A Regimen That Involved Tapering Of The Dose)		Not Reported
	Prednisone	S				Not Reported
	Methylprednisolone	S	Unknown	High Dose		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Glucocorticoids	S	Unknown			Not Reported
	Sulfamethoxazole-Trimethoprim	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589692			Female	CAN

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

Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mirtazapine	S	Unknown	Not Reported
	Mirtazapine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721425	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201801-000313			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	4 Dosage Form, Tablet		Concordia
	Ondansetron Hydrochloride			S	Intravenous (not otherwise specified)	4 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721434	EXPEDITED (15-DAY)		HO, OT	IT-ADVANZ PHARMA-GSH201804-001135			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Back Pain; Blood Lactate Dehydrogenase Increased; C-Reactive	Hydroxychloroquine			S	Oral	Unk		Concordia
	Prednisone			S	Oral	50 Mg, Qd, Administered Initially Which Was Later		Not Reported

Protein Increased; Movement Disorder; Mycobacterial Infection; Mycobacterium Avium Complex Infection; Osteomyelitis; Osteomyelitis; Osteomyelitis Bacterial; Pyrexia	Prednisone	S	Oral	Tapered To 5 Mg/Day 5 Mg		Not Reported
	Ceftriaxone	C				Not Reported
	Ceftriaxone	C				Not Reported
	Ceftriaxone	C				Not Reported
	Ceftriaxone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721454	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245365		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Paracetamol			S	Oral	1 Gr Cada 8 Horas		Ohm Lab
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721456	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245370		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721521	EXPEDITED (15-DAY)		OT	ES-HETERO-HET2020ES00451		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Mg, Qd		Hetero
	Dolquine			S	Oral	200 Mg, Qd		Not Reported
	Metronidazol /00012501/			S	Oral	Unk		Not Reported
	Amoxicilina + Acido Clavulonico			S	Oral	Unk, Tid (1 Comp/8h)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589838		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721569	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi

Methotrexate	S		20 Mg, Qw		Not Reported
Enbrel	S		25 Mg		Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Powder For Solution		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Humira	S	Subcutaneous	40 Mg, Solution Subcutaneous		Not Reported
Actemra	S				Not Reported
Bupropion	C				Not Reported
Sulfasalazine	C				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589413		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721617	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588791		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Sleep Disorder;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Synovitis; Treatment Failure	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Myochrysine		S	Intramuscular	Not Reported
	Orencia		S	Unknown	Not Reported
	Celebrex		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721663	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721692	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588902		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721734	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227334		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg, 1			S	Intravenous (not otherwise specified)	C/24 H		Not Reported

	Ertapenem (2881a)	S	Intravenous (not otherwise specified)	1 Gram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721767	EXPEDITED (15-DAY)		HO, LT, OT	NL-ADVANZ PHARMA-MAPI_00011545			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Oral	Unk, Coated Tablet		Concordia
	Methotrexate			S	Oral	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721865	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004004073			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Unknown	Unk Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721870	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722005	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590161			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722271	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722333	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1227342		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;		Teva
	Amoxicilina Acido Clavulanico Sala			S	Oral	1 Comp/8h		Teva
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	1 Comp/24h, 200 Mg		Not Reported
	Metronidazol (1966a)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722337	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227335		50 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722485	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229997		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Risedronate Sodium			S	Unknown	35 Mg, 1 Every 1 Week		Teva
	Methotrexate			S	Subcutaneous	175 Mg		Barr
	Methotrexate			S	Unknown			Barr

Actemra	S	Subcutaneous			Not Reported
Anakinra	S	Subcutaneous			Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Gold	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Risedronate	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722622	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722635	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA110668		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal;	Adalimumab			S	Subcutaneous	Unk		Novartis
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Ciclosporin Sandoz			S	Oral	Unk		Not Reported
	Cyclosporine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Other (Solution For Injection)		Not Reported

Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate	S	Oral	4 Df, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw (Solution For Injection)	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Unknown	70 Mg, Other	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Other	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk (Oral Solution)	Not Reported
	Apo-Cyclosporine	S	Oral	Unk (Oral Solution)	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apremilast	S	Unknown	Unk	Not Reported
	Apremilast	S	Unknown	60 Mg, Bid	Not Reported
	Apremilast	S	Oral	30 Mg, Bid	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Celebrex	S	Oral	200 Mg, Bid	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Other	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Biw	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Mg, 6qd	Not Reported
	Ibuprofen	S	Oral	600 Mg, Other	Not Reported
	Ibuprofen	S	Oral	600 Mg, Other	Not Reported

Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Other	Not Reported
Motrin	S	Unknown	6 Df, Qd	Not Reported
Motrin	S	Oral	600 Mg, Other	Not Reported
Motrin	S	Oral	600 Mg, Other	Not Reported
Motrin	S	Oral	600 Mg, Other	Not Reported
Motrin	S	Oral	600 Mg, Qd	Not Reported
Motrin	S	Oral	600 Mg, Other	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	Unk (Tablet)	Not Reported
Tocilizumab	S	Unknown	360 Mg, Other	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Cannabis Sativa	C	Unknown	Unk	Not Reported
Actonel	C	Oral	35 Mg, Qw	Not Reported

Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk, Qw	Not Reported
Mogadon	C	Unknown	5 Mg, Other	Not Reported
Naproxen	C	Unknown	500 Mg, Other	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Other	Not Reported
Oxycodone	C	Unknown	10 Mg, Other	Not Reported
Oxycodone	C	Unknown	40 Mg, Other	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Mg, Other	Not Reported
Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Mg, Other	Not Reported
Oxyneo	C	Unknown	40 Mg, Other	Not Reported
Oxyneo	C	Unknown	10 Mg, Other	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Mg, Bid	Not Reported
Uloric	C	Oral	80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Mg, Bid	Not Reported
Vitamin D3	C	Oral	2000 Iu, Other	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228692			Female	CAN

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

Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium	S	Unknown	Actavis
	Prednisone	S	Unknown	Actavis
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589505			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589415			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034249		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram, Qd		Bristol Myers Squibb
	Cimzia			S	Unknown	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

	Prednisone		C	Unknown	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17723476	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590185		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17723713	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020165921		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil Sulfate			S	Oral	600 Mg, 1x/Day		Not Reported

Product Use In
Unapproved Indication

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17724725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Ill-Defined Disorder; Mental Disorder; Muscle Injury; Myalgia; Pruritus; Rash	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725036	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034298		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Abatacept			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium + Vit D			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown	2 Every One Days		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram, Qd		Not Reported
	Tylenol Arthritis Pain			C	Unknown	2 Dosage Form, Bid		Not Reported

	Xarelto			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725448	EXPEDITED (15-DAY)		OT	NVSC2020CA062017		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Joint Swelling; Malaise; Musculoskeletal Stiffness; Nausea; Pain; Spinal X-Ray Abnormal; Stress; Swelling; Tender Joint Count; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725450	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166847		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, Daily		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine [Spiramycin]			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725452	EXPEDITED (15-DAY)		HO, LT, OT	CH-PFIZER INC-2020169681		57 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Advagraf			C	Oral	4 Mg, 1x/Day		Not Reported
	Calcimagon D3			C		Unk		Not Reported
	Cefuroxime			C	Intravenous (not otherwise specified)	1.5 G, 3x/Day		Not Reported
	Co-Amoxicillin			C	Intravenous (not otherwise specified)	1.2 G, 3x/Day		Not Reported
	Flagyl [Metronidazole]			C	Oral	500 Mg, 3x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lasix [Furosemide]			C	Intravenous (not otherwise specified)	40 Mg, 1x/Day		Not Reported
	Myfortic			C	Oral	720 Mg, 2x/Day		Not Reported
	Tazobac			C	Intravenous (not otherwise specified)	2.25 G, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725640	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA202014192			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased;	Human Normal Immunoglobulin			S	Unknown			Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported

Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, 1x/Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, 1x/Day:Qd	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone	S	Oral	10 Milligram, 1x/Day:Qd	Not Reported
	Prednisone	S	Oral	3 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725781	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166844		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Incorrect Product Administration Duration; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Cefotaxime Mylan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725844	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034644		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588805		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589868		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726305	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020924		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Risedronate			S	Unknown	5 Milligram		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported
	Cyclobenzaprine			C	Unknown	10 Milligram		Not Reported

	Desoximetasone		C	Unknown	5 Milligram	Not Reported
	Desoximetasone		C	Unknown	5 Milligram, Once A Day	Not Reported
	Leflunomide		C	Unknown	Unk	Not Reported
	Prednisone Acetate		C	Unknown	5 Milligram, Once A Day	Not Reported
	Tylenol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17727439	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Cardiac Arrest; Cardiogenic Shock; Renal Failure	Hydroxychloroquine (Hydroxychloroquine So4 200mg Tab)			S	Oral			Not Reported
	Azithromycin (Azithromycin 500mg/Vil Inj)			S	Intravenous (not otherwise specified)	Other Strength:500 Mg/Vil;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	12788076	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-077476		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-	Abatacept			S	Subcutaneous	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram,2 Every One Week		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Reactive Protein Increased; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Leflunomide	S	Oral	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Ustekinumab	S	Subcutaneous		Not Reported
	Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
	Apremilast	S	Oral	30 Milligram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Q4h	Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Oral	0.6 Milligram	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Motrin [Ibuprofen]	S	Oral	6 Dosage Form, Qd	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Codeine	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	4 Dosage Form, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Arava	S	Oral	20 Milligram, 1 Every 1 Days	Not Reported
Celebrex	S	Oral	2000 Milligram, 2 Every 1 Days	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported

Folic Acid	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Motrin Children	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown		Not Reported
Methotrexate	C	Oral	Unk, 1 Every 1 Week	Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Cannabis Sativa	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	12887733	EXPEDITED (15-DAY)		OT	CA-ROCHE-1696504		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Prednisone	C			Not Reported
	Ketorolac	C			Not Reported
	Naproxen	C			Not Reported
	Arthrotec	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13058759	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015760		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13976362	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018043		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex

Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Apo-Leflunomide		S	Unknown	25 Mg, Q.Wk.	Apotex
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	25 Mg, Q.Wk.	Not Reported
	Enbrel		S	Unknown	50 Mg, Q.Wk.	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Oral	25 Mg, Q.Wk.	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14633220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-003769		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram 4 Every 1 Week		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported
	Winpred			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Unk		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Etanercept	S	Subcutaneous	50 Milligram		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14667263	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007994		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Off Label Use; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	4000 Iu, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	4000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14784955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108888		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14917260	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Apo-Folic Acid	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	5 Milligram		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Cortisone Acetate	S	Unknown	Unk		Not Reported
Diclofenac	S	Unknown			Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	16323123	EXPEDITED (15-DAY)		OT	AR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-208121		57 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
American Trypanosomiasis; Asthenia; Pyrexia	Prednisone			S	Unknown	40 Milligram, Daily		Mutual
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17261745	EXPEDITED (15-DAY)		OT	IL-GLAXOSMITHKLINE-IL2019EME238237			Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Benlysta			S		Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Clexane			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17262610	EXPEDITED (15-DAY)		OT	PHHY2019GR210755		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Ramipril			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lansoprazole			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17265311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2262233		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use	Actemra			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 11 Years		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Issue; Red Blood Cell Sedimentation Rate Abnormal	Sulfate]					
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Methotrexate		S	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Esomeprazole Magnesium Trihydrate		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported
	Naproxen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17358352	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532032		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Atenolol			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17365297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005932			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17369757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538294			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17433123	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported

Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Solution	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Gold	S			Not Reported
	Plaquenil	S	Oral		Not Reported
	Methotrexate	C	Unknown	Not Sepcified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17433133	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0824		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Healing; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Warfarin	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17450609	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007837		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Thrombosis	Hydroxychloroquine			S	Unknown	200 Mg, Q.12h		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	1000 Mg, Bid		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17656097	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA080271		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria;	Hydroxychloroquine Sulfate			S	Other	600 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	1000 Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi

Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Lovenox	S	Subcutaneous	0.6 Ml, Qd	Sanofi
	Lovenox	S			Sanofi
	Paracetamol	S	Other	4 G, Qd	Not Reported
	Paracetamol	S			Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C	Other	2 Df, Qd	Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C			Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	20 Mg, Qd	Not Reported
	Lasilix [Furosemide]	C	Parenteral	40 Mg, Qd	Not Reported
	Lantus	C	Subcutaneous	20 Iu, Qd	Not Reported
	Pantoprazole	C	Oral	40 Mg, Qd	Not Reported
	Pantoprazole	C			Not Reported
	Pantoprazole	C			Not Reported
	Tienam	C	Intravenous (not otherwise specified)	1 G, Q8h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17692947	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002601			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Ceftriaxone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17702980	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012108			Unknown	CAN

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

Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole	S	Unknown	Not Reported
	Erythromycin	S	Unknown	Bausch And Lomb
	Erythromycin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Bisoprolol	S	Unknown	Not Reported
	Ceclor	S	Unknown	Not Reported
	Celebrex	S	Oral	Not Reported
	Demerol	S	Unknown	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Norfloxacin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arthrotec	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Meperidine Hydrochloride	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726381	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-GSH201806-002096			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Altered State Of Consciousness; Decreased Appetite; Headache; Hypoglycaemia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Cellcept			C		500 Mg, Bid		Not Reported
	Alfacalcidol			C				Not Reported
	Amlodipine			C				Not Reported
	Pantoprazole			C				Not Reported
	Atenololol			C		50 Mg, Freq: Unk X 1 Days		Not Reported
	Prednisolone			C		10 Mg, Freq: Unk X 1 Days		Not Reported
	Furosemide			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Icodextrin			C				Not Reported
	Dianeal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726434	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245618		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1 Puis 250 Mg Par Jour ()		Sun

	Plaquenil		S	Oral	600 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726480	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-E2B_00007901			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram Qt Prolonged; Electrocardiogram U Wave Present; Hypokalaemia; Hypomagnesaemia; Hypotension; Intentional Overdose; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown	60 Tablets, 1200 Mg Total Dose		Concordia
	Oxycodone, Paracetamol			S	Unknown	35 Tablets (5/325 Mg)35 Dosage Form Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726545	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589092			Female	CAN

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

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Cetirizine;Pseudoephedrine	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726564	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589944			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Naproxen	C			Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Lipitor			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726710	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589755			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726980	EXPEDITED (15-DAY)		OT	NL-ACCORD-071584		60 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Treatment Failure	Methotrexate			S				Accord
	Prednisone			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727035	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020168024		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727036	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020167372		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Pr Prolongation; Electrocardiogram T Wave Inversion; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727049	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017786		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589398		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C	Unknown			Not Reported

	Folic Acid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727131	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589814			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown	Tablet (Extendedrelease		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727333	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727336	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

	Phthalylsulphathiazole		S	Unknown	Unk	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727348	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034905			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	1 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Oral	200 Milligram, Qd		Not Reported
	Depo-Medrol With Lidocaine			S	Intra-articular			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Ketoprofen			S	Topical	Unk, Qid		Not Reported
	Leucovorin Calcium			S	Unknown	1 Dosage Form, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Unk		Not Reported
	Prevnar 13			S	Intramuscular	0.5 Milligram, Total		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727372	EXPEDITED (15-DAY)		HO	FR-SA-2020SA111792		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Off Label Use	Plaquenil			S	Oral	600 Mg, Qd		Sanofi
	Plaquenil			S				Sanofi
	Doliprane			S	Oral	4000 Mg, Qd		Not Reported
	Lovenox			S	Subcutaneous	1 Df, Qd		Sanofi
	Azithromycin			S	Oral	1 Df, Qd		Not Reported
	Kaleorid Lp			C	Oral	3 Df, Qd		Not Reported
	Metformin Almus			C	Oral	Unk		Not Reported
	Gliclazide Arrow			C	Oral			Not Reported
	Atorvastatin Arrow			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727386	EXPEDITED (15-DAY)		OT	IT-ACCORD-180018		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Tacrolimus			S				Accord
	Mycophenolic Acid			S				Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Methylprednisolone			C		Unk (Pulses)		Not Reported
	Immunoglobulins (Ivig)			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

	Prednisone	S	Unk Unk (10 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unk Unk (15 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	25 Mg, Qd	Not Reported
	Prednisone	S	Unk (50 Mg Qd, Tapering Dose)	Not Reported
	Prednisone	S	Unk Unk (7.5 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unk (25 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	15 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728025	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728040	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Every 14 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728203	EXPEDITED (15-DAY)		HO	MX-TEVA-2020-MX-1231149		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Nocardiosis; Perinephric Abscess; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram Daily; Scheduled For 2 Months		Teva
	Prednisone			S	Oral	30 Milligram Daily; Scheduled For 2 Months		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram Daily; Scheduled For 2 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728379	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2020AMR072153			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Burning Sensation; Muscle Spasms	Benlysta			S	Unknown	Unk		Glaxosmithkline
	Plaquenil (Hydroxychloroquine)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728437	EXPEDITED (15-DAY)		CA	DE-TEVA-2020-DE-1228290			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Prednisolone			S	Transplacental			Actavis
	Hydroxychloroquine			S	Transplacental			Teva
	Certolizumab			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728554	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus;	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone		S	Unknown		Actavis
	Arava		S	Unknown		Not Reported
	Cetirizine Hydrochloride		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Etanercept		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Powder For Solution For Pre-Filled Syringe	Not Reported
	Tocilizumab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Fosamax	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazol	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Alendronate Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial	25 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728607	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1228759		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure	Acetaminophen			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	40 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram Daily;	Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Intra-arterial	25 Milligram Daily;	Not Reported
Methotrexate	S	Oral	25 Milligram Daily;	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Oral	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Remicade	S	Endocervical		Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Intravenous (not otherwise specified)		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
Topicort	S	Oral		Not Reported

	Topicort	S	Oral	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729022	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020141193		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Hypoaesthesia; Joint Swelling; Muscular Weakness; Nerve Injury; Off Label Use; Pain; Product Use Issue; Sciatica; Spinal Stenosis	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	2 G, Q Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Plaquenil			S	Unknown	400 Mg, Q Unk		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Actonel Xr			C	Unknown	75 Mg Q Unk		Not Reported
	Baclofen			C	Unknown	10 Mg, Daily At Night (Qhs)		Not Reported
	Folic Acid			C	Unknown	5 Mg, 1x/Day		Not Reported
	Lyrica			C	Unknown	75 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	7.5 Mg, 1x/Day		Not Reported
	Vitamin D			C	Unknown	2000 Iu, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729036	NON-EXPEDITED			GR-LUPIN PHARMACEUTICALS INC.-2020-00627		40 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During	Hydroxychloroquine			S	Unknown	Unk		Lupin

Pregnancy	Acetylsalicylic Acid		S	Unknown	Unk	Not Reported
	Prednisolone		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729108	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017788		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729119	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228814			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cortisone Aceta	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729197	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202004240		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sudden Death	Propofol (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Salbutamol			S	Respiratory (inhalation)			Not Reported
	Azithromycin			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Metoclopramide Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported

	Ipratropium Bromide	C	Respiratory (inhalation)	Not Reported
	Enoxaparin Sodium	C	Subcutaneous	Not Reported
	Cefotaxime	C	Intravenous drip	Not Reported
	Midazolam	C	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729226	EXPEDITED (15-DAY)		HO	NVSC2020IN115852		29 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Dysphagia; Mouth Ulceration; Ocular Hyperaemia; Product Use In Unapproved Indication; Skin Exfoliation; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	100 Mg, Bid		Novartis
	Mycophenolate Mofetil			C	Unknown	1.5 G, Bid		Not Reported
	Prednisolone			C	Unknown	30 Mg, Qd		Not Reported
	Prednisolone			C	Unknown	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729374	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000340			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown	Unk		Validus
	Meperidine Hydrochloride			S	Unknown	Unk		Validus
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd (1 Df, Every 1		Not Reported

				Day)	
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729461	EXPEDITED (15-DAY)		OT	NVSC2020IN115930		51 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Product Use In Unapproved Indication; Tinnitus	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisolone			C	Unknown	40 Mg, Qd (Gradual Taper To 5 Mg/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729492	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis;	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Prednisone			S	Unknown			Actavis
	Celebrex			S	Unknown			Not Reported

Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Arava	S	Unknown			Not Reported
	Belimumab	S	Unknown			Not Reported
	Breo Ellipta	S	Respiratory (inhalation)			Not Reported
	Colchicine	S	Unknown			Not Reported
	Dexilant	S	Oral	60 Milligram Daily;		Not Reported
	Estrogel	S	Topical			Not Reported
	Methotrexate	S	Oral			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ventolin Hfa	S	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729669	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020171686		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Off Label Use; Product Use In Unapproved Indication; Tachyarrhythmia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ceftriaxon			C	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729799	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020171243		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine Hcl			S	Oral	225 Mg, 1x/Day		Pfizer
	Loxapine			S	Oral	155 Mg, 1x/Day		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day	Not Reported
Theralene	S	Oral	50 Mg, 1x/Day	Not Reported
Paracetamol	C	Oral	1 G, 1x/Day	Not Reported
Akineton [Biperiden Hydrochloride]	C	Oral	4 Mg	Not Reported
Macrogol 4000	C	Oral	Unk	Not Reported
Atorvastatin	C	Oral	40 Mg, 1x/Day	Not Reported
Ezetimibe	C	Oral	10 Mg, 1x/Day	Not Reported
Kardegic	C	Oral	75 Mg, 1x/Day	Not Reported
Nebivolol	C	Oral	7.5 Mg, 1x/Day	Not Reported
Ramipril	C	Oral	1.25 Mg, 1x/Day	Not Reported
Diazepam	C	Oral	10 Mg, 1x/Day	Not Reported
Nicopatch	C	Transdermal	7 Mg, 1x/Day	Not Reported
Nicotine	C	Oral	12 Mg, 1x/Day	Not Reported
Zopiclone	C	Oral	7.5 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729886	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020171246		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Effexor Lp			S	Oral	150 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Risperidone			S	Oral	2 Mg, 1x/Day		Not Reported
	Acebutolol Hydrochloride			C	Oral	400 Mg, 1x/Day		Not Reported
	Oxazepam			C	Oral	100 Mg, 1x/Day		Not Reported
	Sodium Enoxaparin			C	Subcutaneous	4000 Iu, 1x/Day		Not Reported
	Macrogol 4000			C	Oral	2 Df, 1x/Day		Not Reported
	Amlodipine			C	Oral	10 Mg, 1x/Day		Not Reported
	Clomipramine Hydrochloride			C	Oral	150 Mg, Monthly		Not Reported

Zopiclone	C	Oral	7.5 Mg, 1x/Day		Not Reported
Nicardipine Hydrochloride	C	Oral	60 Mg, 1x/Day		Not Reported
Hydrochlorothiazide	C	Oral	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729999	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017804		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram,Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S		125 Milligram, Weekly (Qw)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Monthly (Qm)		Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	5mg 2every 1day		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730004	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide	Acetaminophen			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Actavis

Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S			Barr
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported

Methotrexate Sodium	S	Oral			Not Reported
Methotrexate Sodium	S	Oral			Not Reported
Methotrexate Sodium	S	Oral			Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S				Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]]	S	Oral	400 Milligram Daily;		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Reactine (Cetirizine)	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Sarilumab	S	Unknown			Not Reported
Simponi	S	Subcutaneous			Not Reported
Stelara	S	Unknown			Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfathalidine	S	Unknown			Not Reported
Topicort	S	Unknown			Not Reported
Topicort	S	Subcutaneous			Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C				Not Reported
Salazopyrina	C				Not Reported
Tofacitinib Citrate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590432		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension;	Actemra			S	Unknown			Not Reported

Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Sleep Disorder	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730396	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling;	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methotrexate	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Depomedrol	C	Intramuscular	Not Reported
	Diclofenac	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730404	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012542		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus	Diclofenac			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquin			S	Unknown			Not Reported

Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednison	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Salazopyrine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590245		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip	365.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	731.0		Not Reported

Sensitivity To Weather Change; Toe Amputation	Hydroxychloroquine		S	Oral		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Methotrexate		S	Oral		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Oral		Not Reported
	Restasis		C	Unknown	Emulsion	Not Reported
	Synthroid		C	Unknown		Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730976	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588779		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	11720121	EXPEDITED (15-DAY)		DS	CA-ROCHE-1657676			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	12844829	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1042716		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate			S		7.5 Mg, Cycle (10 Days)		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Not Reported
	Certolizumab Pegol			S		200 Mg, Biweekly		Mylan

	Certolizumab Pegol	S	1 Df, Q21d	Mylan
	Bromazepam	C	Unk	Mylan
	Bromazepam	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13216626	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890689		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13657150	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA105823		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi

Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Oral	Unk Unk,Unk	Sanofi
	Minocycline Hydrochloride	S			Not Reported
	Minocycline Hydrochloride	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Arava	S			Sanofi
	Arava	S			Sanofi
	Leflunomide	S			Sanofi
	Leflunomide	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Plaquenil	S			Sanofi
	Plaquenil	S		400 Mg	Sanofi
	Oxycodone	S		10 Mg	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S		Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S		Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported

Enbrel	S		Unk Unk,Unk		Not Reported
Marijuana	S				Not Reported
Xeljanz	S		Oral	Unk Unk, Bid	Not Reported
Gold	S				Not Reported
Ilaris	S		Subcutaneous	Unk Unk,Unk	Not Reported
Ilaris	S		Subcutaneous	Unk Unk,Unk	Not Reported
Hydroxychloroquine Phosphate	C		Unknown	Unk Unk,Unk	Not Reported
Rituximab	C			Unk	Not Reported
Anakinra	C			Unk	Not Reported
Lyrica	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13868474	EXPEDITED (15-DAY)		OT	CA-ROCHE-1976526		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730.0 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16066887	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1022788		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral	Unk		Not Reported
	Coversyl /00790702/			S	Oral	Unk		Mylan
	Coversyl /00790702/			S	Unknown	Unk Unk,Unk		Mylan
	Plaquenil /00072603/			S	Oral	200 Mg/ Day		Mylan
	Cortancyl			S	Oral	10-20µg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16217782	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190424225		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Remicade			S				Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Cyclosporine			S				Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

Methotrexate	S		Not Reported
Methotrexate	S		Not Reported
Amlodipine	S	Unknown	Not Reported
Cyclophosphamide	S	Unknown	Not Reported
Enalapril	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Metformin	S	Unknown	Not Reported
Nutropin	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Protropin	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16693247	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208351		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Plaquenil			S	Oral	400 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Codeine			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Adalimumab			S	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported

Decreased; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qm	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Unknown	30 Mg, Qw	Not Reported
	Prednisone	C		35 Mg, Qd	Not Reported
	Xeljanz	C	Unknown	Unk Unk, Unk	Not Reported
	Simponi	C	Subcutaneous	50 Mg	Not Reported
	Adalimumab	C		Unk	Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16693818	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208304		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S		640 Mg, Unk		Not Reported
	Actemra			S		640 Mg, Unk		Not Reported
	Actemra			S		640 Mg, Qw		Not Reported

Apo-Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk Unk, Unk	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg For 9.0 Month(S)	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg For 9.0 Month(S)	Not Reported
Ciclosporin	S	Oral	Unk Unk, Unk	Not Reported
Ciclosporin	S	Oral		Not Reported
Ciclosporin	S	Oral		Not Reported
Cimzia	S	Subcutaneous	200 Mg, Single-Use Prefilled Syringe	Not Reported
Cimzia	S	Subcutaneous	200 Mg Qw, Single-Use Prefilled Syringe	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Unk For 4 Years	Not Reported
Gold	S	Unknown	Unk Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qw For 4 Years	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Qw	Not Reported
Imuran [Azathioprine Sodium]	S	Unknown	Unk Unk, Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw For 2 Years	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Simponi	S	Unknown	Unk Unk, Unk	Not Reported
Rituxan	S	Unknown	Unk Unk, Unk	Not Reported
Piroxicam	C			Not Reported
Prednisone	C		Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16805798	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201908000239			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Eye Haemorrhage; Weight Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Dupixent			S	Subcutaneous	Unk Loading Dose		Not Reported
	Dupixent			S	Subcutaneous	300 Mg, Qow		Not Reported
	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17027053	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA305395		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone Acetonide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qow		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S		1.3 Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk, Unk		Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 G, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17033136	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2019SA308981		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S	Intra-articular	Unk		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Naproxen			S		Unk		Not Reported
	Naproxen			S	Oral	3 Mg, Qd		Not Reported
	Naproxen			S	Oral	5 Mg, Qd		Not Reported
	Naproxen			S	Unknown	Unk Unk, Unk		Not Reported
	Naproxen			S				Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	50 Mg, Bid		Not Reported
	Prednisone			S		50 Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported

Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Prednisone	S	Oral	1.3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Qw	Not Reported
	Methotrexate	S		Unk Unk, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qow	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Q6w	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
	Infliximab	S		Unk Unk, Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk, Q6w	Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Kineret	S	Subcutaneous	Unk Unk, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported

Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Qm	Not Reported
Orencia	S	Intravenous drip	250 Mg, Q2m	Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Orencia	S	Respiratory (inhalation)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Unk	Not Reported
Orencia	S		Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S		Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qod	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Etanercept	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Etanercept	S	Subcutaneous	25 Mg, Biw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported

	Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Abatacept	S	Intravenous drip	250 Mg, Qm	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S		Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S		50 Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S		Unk	Not Reported
	Orencia	S			Not Reported
	Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17069951	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001908			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bacterial Infection; Contusion; Cystitis; Fatigue; Feeling Abnormal; Hemiparesis; Hysterectomy; Insomnia; Pain; Pain In Extremity; Ph Body Fluid Abnormal; Pyrexia; Tremor; Vaginal Haemorrhage; Vulvovaginal Mycotic Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Teriflunomide			S	Oral	14 Mg, Qd (Coated Tablet)		Not Reported
	Teriflunomide			S	Oral	14 Mg, Qd		Not Reported
	Fludrocortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17419878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543667		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17653955	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-017958		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Lopinavir;Ritonavir			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported

	Prednisone		C	Oral	20 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17716072	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-020311		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome; Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Salbutamol			S	Respiratory (inhalation)	0.1 Milligram, Four Times/Day		Not Reported
	Dolquine			S	Oral	400 Milligram, Two Times A Day		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)	10 Milligram, 3 Times A Day		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	20 Microgram, Four Times/Day		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Cefotaxime			C	Intravenous drip	4 Gram, Two Times A Day		Not Reported
	Midazolam			C	Intravenous drip	100 Milligram, Once A Day		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17721946	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227338		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

	Dolquine	S	Oral	400 Milligram Daily; Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported
	Dolquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17724166	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166893		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731661	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004082			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Ear Pain; Eye Injury; Headache; Herpes Virus Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589712		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731830	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588961		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732413	EXPEDITED (15-DAY)		HO	CA-ROCHE-2587291		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Apo Amlo			C	Unknown			Not Reported
	Apo-K			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Epoetin Alfa			C	Unknown			Not Reported
	Escitalopram			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Insulin Lispro			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Kcl			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported

Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Methylprednisolone	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Slow-K	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Ventolin [Salbutamol]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589459		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Duration 4 Month		Not Reported
	Methotrexate			S	Unknown	Duration 4 Month		Not Reported
	Orencia			S	Unknown	Duration 4 Month		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Duration 4 Month		Not Reported
	Prednisone			S	Unknown	Duration 4 Month		Not Reported
	Remicade			S	Unknown	Duration 4 Month		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Duration 4 Month		Not Reported
	Simponi			S	Subcutaneous	Duration 4 Month		Not Reported

	Xeljanz			S	Oral	Duration 4 Month			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732474	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003662			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732521	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002893			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733312	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229092		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733315	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229034		37 YR	Female	CAN

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

Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Ivax
	Methotrexate	S	Unknown	Barr
	Mycophenolate Mofetil	S	Unknown	Teva
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733337	EXPEDITED (15-DAY)		HO	ES-BAYER-2020-066313		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Betaferon			S	Subcutaneous	0.25 Mg		Bayer
	Betaferon			S				Bayer
	Dolquine			S	Oral	400 Mg Dia		Not Reported
	Kaletra			S	Oral	2 Df, Bid		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733717	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3387130-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733894	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588759			Male	CAN

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

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734070	NON-EXPEDITED		HO, OT	PL-AMGEN-POLSP2020070504		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Encorton [Prednisone Acetate]			S	Unknown	15 Milligram, Qd		Not Reported
	Encorton [Prednisone Acetate]			S	Unknown	10 Milligram, Qd		Not Reported
	Plaquenil S			S	Unknown	20 Milligram, Qd		Not Reported
	Erelzi [Etanercept]			S	Intravenous (not otherwise specified)	50 Milligram		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Metex [Methotrexate Sodium]			C	Subcutaneous	Unk (The Last Injection In Jan-2019))		Not Reported
	Folic Acid			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734176	EXPEDITED (15-DAY)		DE, OT	CH-SA-2020SA109443		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Off Label Use; Thrombocytopenia; Thrombotic Microangiopathy	Plaquenil			S	Oral	800 Mg/Day From 22 To 23 Mar 2020, 400 Mg/Day From 24 To 26 Mar 2020, 600 Mg/Day From 26 To 30 Mar 2		Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S	Oral	200 Mg		Not Reported
	Azithromycin			S	Oral	250 Mg		Not Reported
	Amoxicillin Trihydrate/Potassium Clavulanate			S	Intravenous drip	3.6 G, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg		Sanofi
	Fentanyl			S	Transdermal	25 Ug/H		Not Reported
	Piperacillin + Tazobactam			C	Intravenous (not otherwise specified)	13.5 G		Not Reported
	Paracetamol			C		500 Mg, Qid		Not Reported
	Paracetamol			C		500 Mg		Not Reported
	Humulus Lupulus Extract;Valeriana Officinalis Extract			C				Not Reported
	Macrogol			C		Unk Unk, Qd		Not Reported
	Metoclopramide			C		10 Mg, Tid		Not Reported
	Relaxane			C		Unk Unk, Tid		Not Reported
	Supradyn [Minerals Nos;Vitamins Nos]			C		Unk Unk, Qd		Not Reported
	Redormin [Remifentanil Hydrochloride]			C		500 Mg, Qd		Not Reported
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734253	EXPEDITED (15-DAY)		OT	CA-SA-2020SA112718		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S		Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg		Sanofi
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Oral	1000 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Golimumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfathalidine	S	Unknown	Unk		Not Reported
	Diclofenac	C		Unk		Not Reported
	Salazopyrin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734523	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2020171826		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Zithromax			S	Other	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734550	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020171235		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734833	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported

Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Oral	Not Reported
	Zyrtec-D	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported

	Sulfathalidine	S	Unknown	Not Reported
	Topicorten	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17735719	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-012941		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Cortisone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Topicort			S	Subcutaneous			Not Reported
	Topicort			S	Unknown			Not Reported
	Topicort			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride,			S	Unknown			Not Reported

Pseudoephedrine Hydrochloride				
Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Leflunomide Sandoz	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Intra-arterial		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Sulfathalidine	S	Subcutaneous	Not Reported
Tofacitinib Citrate	S	Subcutaneous	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported

	Cortisone Acetate	S	Topical	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Atasol [Paracetamol]	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17735914	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Diltiazem Hydrochloride			C	Oral			Not Reported

	Fluticasone Propionate	C	Respiratory (inhalation)		Not Reported
	Mar-Pantoprazole	C	Unknown	Tablet (Delayed Release)	Not Reported
	Mometasone Furoate	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Salbutamol Sulfate	C	Respiratory (inhalation)		Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736149	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020176534			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Cancer	Xeljanz Xr			S		11 Mg, 1x/Day (11mg Qd)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736216	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Topicort			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not	Not Reported

			otherwise specified)	
	Rituximab	S	Intravenous drip	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
	Salazopyrina	C		Not Reported
	Tofacitinib Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736256	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported

Pantoprazole	S	Oral			Not Reported
Pantoprazole Magnesium	S	Unknown			Not Reported
Synthroid	S	Unknown			Not Reported
Premarin	C	Unknown			Not Reported
Tramadol Hydrochloride	C	Oral			Not Reported
Salbutamol Sulfate	C	Respiratory (inhalation)			Not Reported
Mometasone Furoate	C	Unknown			Not Reported
Mar-Pantoprazole	C	Unknown	Form Of Admin: Tablet (Delayed-Release)		Not Reported
Fluticasone Propionate	C	Respiratory (inhalation)			Not Reported
Diltiazem Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736716	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-021403		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day(Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day(Dia)		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Tocilizumab			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day(Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736737	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-093087		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported
	Actonel			S	Unknown	35 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			C	Unknown	300 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736746	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2020-021570		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxona			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Dolquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Metilprednisolona			S	Intravenous (not	250 Milligram, Once A Day		Not Reported

	Tocilizumab		S	otherwise specified) Intravenous (not otherwise specified)	560 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	15369646	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181868		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	16139048	EXPEDITED (15-DAY)		OT	DE-ACCORD-117446		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Methotrexate			S	Subcutaneous	20 Mg, Tablet Oral		Accord
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Powder For Solution Intravenous		Not Reported
	Leflunomide			S		Film-Coated Tablet		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Neoral			S	Subcutaneous			Not Reported

Neoral	S	Oral		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Apo-Leflunomide	S	Oral	Also Received Additionally, Film Coated Tablet	Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Also Received Oral Tablet	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Apo-Hydroxyquine	S	Oral	Unk, Also Received Subcutaneous Apo-Hydroxyquine Thrice	Not Reported
Rituxan	S	Unknown	Solution Intravenous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736773	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2020-021363		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form (2u/2 H)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736776	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019740		77 YR	Female	ITA

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

Off Label Use; Thrombocytopenia	Azithromycin	S	Oral	500 Milligram, Once A Day	Aurobindo
	Clexane	S	Subcutaneous	4 Kilo-International Unit, Once A Day	Not Reported
	Plaquenil	S	Oral	600 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736804	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020847		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	800 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736808	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-020857			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736838	EXPEDITED (15-DAY)		HO	ES-HETERO-HET2020ES00483		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg, Qd		Hetero
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Kaletra			S	Oral	12 Hours Bid (200/50mg)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587376		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736873	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-020465		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Haloperidol			S	Oral	5 Gtt Drops, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736886	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1228537		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycine Anhydre			S	Oral	250 Mg		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported
	Rocephine			S	Oral	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737066	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000161			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Heparin			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torasemide			S	Transplacental			Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Dalteparin Sodium			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-		Not Reported

			14	
Simvastatin	S	Transplacental		Not Reported
Clexane	S	Transplacental	From Gestational Week 0-14, 200 Mg/D (2x100)	Not Reported
Salbutamol Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Salbutamol Sulfate	S	Transplacental		Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental		Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Xarelto	S	Transplacental		Not Reported
Pantoprazole	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental		Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental		Not Reported
Ramipril	S	Transplacental	20 Mg, Qd From Gestational Week 0-113+6	Not Reported
Ramipril	S	Transplacental	Maternal Dose 20 Mg, Unk	Not Reported
Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported

Aliskiren	S	Transplacental			Not Reported
Aliskiren	S	Transplacental			Not Reported
Metamizole Sodium	S	Transplacental	From Gestational Week 0-14		Not Reported
Metamizole Sodium	S	Transplacental			Not Reported
Misoprostol	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5		Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional		Not Reported
Mifepristone	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
Enoxaparin Sodium	S	Transplacental	(From Gestational Week 0-14)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737105	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Kevzara			S	Subcutaneous			Not Reported

	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Magnesium	C			Not Reported
	Metformin	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737152	EXPEDITED (15-DAY)		DE, OT	DE-TEVA-2020-DE-1229088		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram Daily; 1-0-1		Teva
	Hydroxychloroquine			S				Teva
	Azithromycin			C				Not Reported
	Azithromycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737198	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1229150		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	800mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	14308678	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050900		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Cimzia			S	Subcutaneous	Unk		Not Reported

Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Cimzia	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S		Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Weekly (Qw)	Not Reported
	Methotrexate	C	Oral	25 Mg, Weekly (Qw)	Not Reported
	Plaquenil	C		200 Mg, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737230	EXPEDITED (15-DAY)		HO	CA-ROCHE-2590268		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737254	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590321		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737289	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported

Intolerance	Arava	S	Oral		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737316	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020161825		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	12182291	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1723643		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete;	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 2.0 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported

Viral Infection	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Urethral		Not Reported
	Methotrexate Sodium	S	Oral	(2.5 Mg- 8 Tablets Orally Once Weekly)	Not Reported
	Methotrexate Sodium	S	Unknown	Solution For Injection	Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 24.0 Year(S)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate	S	Oral	Therapy Duration 24.0 Years	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Solution For Injection	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Cymbalta	C			Not Reported
	Methotrexate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13976657	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018044		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, 1 Every 2 Week		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex

	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	12.5 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, 1 Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Q.M.T.	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14235971	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021661		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Prednisone	C	Oral	6 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Advil /00044201/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14747260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105393		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Caffeine;Codeine;Paracetamol			S	Unknown			Not Reported
	Tylenol No.2			S	Unknown			Not Reported
	Dorzolamide			S	Ophthalmic			Not Reported

Hydrochloride/Timolol Maleate				
Dorzolamide	S	Ophthalmic		Not Reported
Hydrochloride/Timolol Maleate				
Dorzolamide	S	Unknown		Not Reported
Hydrochloride/Timolol Maleate				
Dorzolamide	S	Unknown		Not Reported
Hydrochloride/Timolol Maleate				
Folic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Levothyroxine	S	Unknown		Not Reported
Levothyroxine	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Prednisone	S	Unknown		Not Reported
Ramipril	S	Unknown		Not Reported
Cosopt	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Codeine Phosphate	S	Unknown		Not Reported
Codeine	S	Unknown		Not Reported
Diphenhydramine	C			Not Reported
Methylprednisolone	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
Tylenol	C			Not Reported
Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14815456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111505		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15268961	EXPEDITED (15-DAY)		HO	CA-ROCHE-2166736		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15342993	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176790		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Arthritis; Sciatica	Apo-Folic Acid	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Ramipril	S	Unknown	Not Reported
	Apo-Ramipril	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16119797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027001		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Eye Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event;	Orencia			S	Unknown	Therapy Duration 10.0 Month(S)		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Therapy Duration 30 Days		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration 6.0 Years		Not Reported
	Leflunomide			S	Unknown	62.0 Days		Not Reported
	Methotrexate			S	Unknown	123 Days		Not Reported

Weight Decreased	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16641652	EXPEDITED (15-DAY)		OT	CA-ROCHE-2361846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17250187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513966		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling;	Actemra			S	Unknown			Not Reported

Pneumonia; Treatment Failure	Rituximab	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syring, Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Infliximab	S	Unknown		Not Reported
	Cefalexin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17454345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007815		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Desoximetasone	C	Unknown	10 Mg, Qd		Not Reported
	Diclofenac	C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17662224	EXPEDITED (15-DAY)		DE, HO, OT	SK-GLAXOSMITHKLINE-SK2020061907		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Cyclosporine A			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17674805	EXPEDITED (15-DAY)		DE, HO, OT	SK-ORION CORPORATION ORION PHARMA-20_00008910		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Jc Virus Infection; Mental Impairment; Pneumonia; Product Use In Unapproved Indication; Progressive Multifocal	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cyclosporine A			S	Unknown			Not Reported

Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Belimumab	S	Unknown	Not Reported
	Cyclophosphamide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17684289	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1038428		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	12.5 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S		1 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Mylan
	Envarsus			S	Unknown	Unk, Qd		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			S	Unknown	1 Dosage Form, Qd		Mylan
	Rituximab			C		Unk		Mylan

	Methylprednisolone	C	Unk (Pulses)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17722247	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulphathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17737409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589933		59 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739425	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular	Dosage Form: Suspension Intra-Articular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739633	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Humira			S	Subcutaneous					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort [Desoximetasone]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739663	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form Of Admin: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depomedrol			C	Intramuscular	Form Of Admin: Suspension For Infusion		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739747	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245893		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Sun
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739833	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1945		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Flexeril			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Visanne			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739836	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1679		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Gait Disturbance; Joint Swelling; Muscular Weakness; Nerve Injury; Pain; Paraesthesia; Rheumatoid Arthritis; Sciatica; Spinal Stenosis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Q Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Q Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actonel Xr			C	Unknown	Every Unspecified Unit (Q)		Not Reported
	Baclofen			C	Unknown	Every Night (Hs)		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

Prednisone	C	Oral	Not Reported
Vitamin D	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739900	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245906		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Mg Dia ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740011	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2020-00693		31 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	5 Milligram/Kilogram		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740014	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01594		64 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740015	NON-EXPEDITED		LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-01647		50 YR	Female	USA

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

	R Chop	C	Unknown	Unk		Not Reported
	Doxorubicin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740016	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2020-00911		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740017	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01472			Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740069	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004409			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hand Fracture; Hip Fracture; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740109	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201812000036			Unknown	CAN

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

Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Hydroxychloroquine	S	Unknown	Unk, Tablet	Concordia
	Arava	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	C			Not Reported
	Acetaminophen And Codeine Phosphate	C		Unk	Not Reported
	Cimzia	C		Unk	Not Reported
	Humira	C		Unk	Not Reported
	Orencia	C		Unk	Not Reported
	Actemra	C		Unk	Not Reported
	Simponi	C		Unk	Not Reported
	Lyrica	C		Unk	Not Reported
	Arthrotec	C		Unk	Not Reported
	Tylenol	C		Unk	Not Reported
	Rabeprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740137	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2020-DE-1229760		71 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Off Label Use	Hydroxychloroquine			S	Oral	1200 Milligram Daily;		Teva
	Hydroxychloroquine			S		200 Milligram Daily;		Teva
	Hydroxychloroquine			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740608	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740669	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245901		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740724	EXPEDITED (15-DAY)		DE, OT	ES-GLAXOSMITHKLINE-ES2020073213		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Sudden Death	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, Tid		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, Qid		Glaxosmithkline
	Azithromycin			S	Oral	500 Mg, Qd		Glaxosmithkline
	Dolquine			S	Oral	400 Mg		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported

Cefotaxim	C	Intravenous drip	4 G, Bid		Not Reported
Tocilizumab	C	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
Midazolam	C	Intravenous drip	100 Mg, Qd		Not Reported
Ipratropii Bromidum	C	Respiratory (inhalation)	20 ?G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740754	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201907-001630			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Eruption; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Epstein-Barr Virus Infection Reactivation; Face Oedema; Leukocytosis; Oedema Peripheral; Pyrexia; Rash; Rash; Rash; Rash Pruritic; Rebound Effect; Transaminases Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Methylprednisolone			S	Unknown	60 Mg, Qid		Not Reported
	Methylprednisolone			S	Unknown	80 Mg, Bid		Not Reported
	Methylprednisolone			S	Oral	Unkunknown (Tapered To Oral Methylprednisolone)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Caffeine	C		Not Reported
	Codeine Phosphate	C		Not Reported
	Meprobamate	C		Not Reported
	Dorzolamide Hydrochloride	C		Not Reported
	Timolol Maleate	C		Not Reported
	Folic Acid	C		Not Reported
	Levothyroxine	C		Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C		Not Reported
	Ramipril	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591475			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588677		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Multiple System Atrophy	Actemra			S	Intravenous (not otherwise specified)	Duration 7 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Duration 579		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Cyclical Duration 2 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	1 In1 Week		Not Reported
	Methotrexate			S	Subcutaneous	1 In1 Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Duration:7.0 Months		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740840	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Desoximetasone			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi

Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Oral			Not Reported
	Plaquenil	S		400 Ml, Qd		Sanofi
	Prednisone	S				Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Adalimumab	S	Subcutaneous			Not Reported
	Phthalylsulfathiazole	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Etanercept	S	Subcutaneous			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Tocilizumab	S				Not Reported
	Tofacitinib Citrate	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740849	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590808		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740856	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591172		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Infusion		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591821		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache;	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Rheumatoid Arthritis; Treatment Failure; Viral Infection	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741579	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171234		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	Unk		Pfizer
	Hydroxyzine Arrow			S	Oral	25 Mg, Single		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741728	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-035310			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741744	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589836		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Spinal Operation; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591992			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Mobicox			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Meloxicam			S	Oral			Not Reported

	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741908	EXPEDITED (15-DAY)		DS	CA-ROCHE-2590957		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Headache; Impaired Work Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Peripheral Swelling; Skin Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742198	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Naproxen	S	Unknown	Teva
	Anakinra	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Lasix [Furosemide]	C		Not Reported
	Methylprednisolone	C		Not Reported
	Naprosyn [Naproxen]	C		Not Reported
	Oxycontin	C		Not Reported
	Oxyneo	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742242	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230038			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine Phosphate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742305	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230007		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Unknown			Not Reported
	Arthrotec			C				Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742309	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230224			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Tissue Swelling	Enbrel	S	Unknown	Not Reported
	Gold	S	Other	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742317	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230103			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported

	Xeljanz			C	Oral	10 Ml Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742319	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1229996		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742383	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Aluminum Acetate	C		Not Reported
	Atacand	C	Unknown	Not Reported
	Benzethonium Chloride	C		Not Reported
	Neurontin	C	Unknown	Not Reported
	Ergocalciferol	C		Not Reported
	Folic Acid	C		Not Reported
	Hydrodiuril	C		Not Reported
	Premarin	C		Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742438	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230239			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arthrotec			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lipitor			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Dovobet	C	Topical	Not Reported
	Flovent	C	Respiratory (inhalation)	Not Reported
	Folic Acid	C	Oral	Not Reported
	Multi Vitamin	C	Oral	Not Reported
	Omeprazole	C	Oral	Not Reported
	Ventolin	C	Respiratory (inhalation)	Not Reported
	Vitamin D2	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742609	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1043063			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Abnormal; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Not Reported
	Kiovig			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742756	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230080		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Tocilizumab	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Prednisone	C	Unknown	12 Milligram Daily;	Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742810	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1230043		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling;	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported

Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Arava	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742993	EXPEDITED (15-DAY)		HO	SE-MYLANLABS-2020M1043195		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram		Not Reported
	Prednisolone			S	Oral	10-15st.		Not Reported
	Plaquenil /00072603/			S	Oral	10-15 St.		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743520	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1230201			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement;	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Oxycodone			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Stomatitis; Thrombosis; Urticaria	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Marijuana	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743532	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230195		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Enbrel		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]		S	Unknown	400 Milligram Daily;	Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	2 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743534	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1230217		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis;	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Alendronate Sodium			S	Unknown			Actavis

Skin Ulcer; Therapeutic Response Decreased; Ulcer	Codeine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230200		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug	Leflunomide			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Adalimumab			S	Unknown			Not Reported

Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Minocycline	C	Unknown	Not Reported
	Penicillamine	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Tocilizumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743595	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230196		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Factor Positive	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Azathioprine		C	Unknown		Not Reported
	Arthrotec		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Gold		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745001	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Hydroxychloroquine			S	Oral			Actavis
	Actemra	Y		S	Intravenous bolus	Other Frequency:X1;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230094		59 YR	Male	CAN

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

Intolerance; Headache; Rheumatoid Arthritis; Tremor	Adalimumab	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir	C	Unknown	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745147	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230084			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspnoea; Hypertension; Neoplasm Malignant	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230198		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Diclofenac			C	Unknown	100 Milligram Daily;		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Voltaren [Diclofenac]			C	Unknown	100 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230102		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity;	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Subcutaneous	Barr
	Methotrexate	S	Subcutaneous	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported
	Vitamin D [Colecalciferol]	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745153	EXPEDITED (15-DAY)		DE, LT	CA-TEVA-2020-CA-1230049		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate Sodium			S	Unknown			Barr
	Minocycline			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Ilaris	C	Unknown	Not Reported
Ilaris	C	Subcutaneous	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745155	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1230197		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine Sulfate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Ciclosporin		C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone		C	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Xeljanz			S				Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Tofacitinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745174	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3388205-00		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Renal Impairment	Kaletra 200/50			S	Oral			Not Reported
	Ciclosporina			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745245	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034937		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actonel			S	Oral	35 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qd		Not Reported
	Hydroxychloroquine			C	Oral	400 Milligram, Qd		Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745333	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022011		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis	Azithromycin			S	Oral	500 Milligram, Once A Day, (500 Mg Dia)		Aurobindo
	Hidroxicloroquina			S	Oral	400 Milligram, Once A Day, (400 Mg Dia)		Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745350	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232076		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			C		300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745363	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232129		56 YR	Female	CAN

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

Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Leflunomide	S	Unknown	1 Dosage Forms Daily;	Barr
	Methotrexate	S	Subcutaneous		Barr
	Risedronate Sodium	S	Unknown		Teva
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Forms Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	12326256	EXPEDITED (15-DAY)		OT	CA-ROCHE-1750136		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased; Therapeutic Response Decreased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Therapy Duration: 365 Nos		Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 880 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 20 Years		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Upper Respiratory Tract Infection	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral	12.0 Months	Not Reported
	Methotrexate Sodium	S	Oral	20.0 Years	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Infliximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	12590542	EXPEDITED (15-DAY)		OT	CA-ROCHE-1627133		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Arava			S	Oral	Frequency: Every 1 Day		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Every Day Besides Sunday		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13067385	EXPEDITED (15-DAY)		OT	CA-ROCHE-1871931			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13187329	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886111		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Disturbance; Haemorrhage; Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	14815367	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712238		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Actemra			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Year(S)		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 2 Months		Not Reported

Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral	Duration: 8.0 Months	Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Methotrexate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	14917304	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093137		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Apo-Warfarin		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown		Not Reported
	Anakinra		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Warfarin		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15331158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176740		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15386769	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-20713376		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15412303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186769			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Varenicline Tartrate	S	Oral	Not Reported
	Varenicline Tartrate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15450369	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral			Not Reported
Folic Acid	C	Unknown	Dosage Forms : 1.0		Not Reported
Prednisone	C	Unknown			Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15619576	EXPEDITED (15-DAY)		HO, OT	GR-ACCORD-091884		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Methotrexate			S	Unknown	15 Mg, Qw		Accord
	Citalopram			S	Unknown			Not Reported
	Captopril			S				Not Reported
	Alprazolam			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Mg, Qw		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Adalimumab			S				Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Valsartan			C				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16359788	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03160		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Losartan			C	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16691209	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Sanofi
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16696905	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2019SA208335		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi

Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Hydroxychloroquine	S		Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S	Oral	Unk Unk, Unk	Sanofi
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk Unk, Unk	Not Reported
	Plaquenil	S		Unk Unk, Unk	Sanofi
	Plaquenil	S		Unk Unk, Unk	Sanofi
	Sulfasalazine	S		Unk Unk, Unk	Not Reported
	Sulfasalazine	S		500 Mg, Unk	Not Reported
	Sodium Aurothiomalate	S		Unk Unk, Unk	Not Reported
	Sodium Aurothiomalate	S		Unk Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk, Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Gold	S	Unknown	Unk Unk, Unk	Not Reported
	Humira	S		Unk Unk, Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Orencia	S		Unk Unk, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Remicade	S		Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituxan	S		Unk Unk, Unk	Not Reported

	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituximab;Urelumab		C		Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16884494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2417965		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mol		Not Reported
	Wellbutrin			C	Unknown	Tablet (Extendedrelease)		Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17241867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511098		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Tocilizumab	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17245016	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2511679		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Jaundice; Joint Swelling; Nausea; Platelet Count Increased; Rheumatoid Arthritis; Treatment Failure; Vitamin D Decreased; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Rosuvastatin	C	Unknown	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Ergocalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17259884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518729		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17278764	EXPEDITED (15-DAY)		OT	NVSC2019CA086426		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug	Diclofenac			S	Unknown	50 Mg		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Diethylamine			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported

Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Live Birth; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Folic Acid	S	Unknown	0.5 Unk	Not Reported
	Folic Acid	S	Oral	25 Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	50 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Cimzia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	400 Mg, Qw	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Biw	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Salazopyrine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Qd	Not Reported
Paracetamol	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Winpred	S	Oral		Not Reported
Stelera	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17594370	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085524		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Ilaris	S	otherwise specified) Subcutaneous	Unk		Novartis
	Actemra	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Anakinra	S				Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Arava	S				Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17598822	EXPEDITED (15-DAY)		LT	NVSC2020CA085528		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Thrombosis	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown	Not Reported
	Urelumab	C	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17662286	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ADVANZ PHARMA-202003002885			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; General Physical Health Deterioration; Off Label Use; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17688286	EXPEDITED (15-DAY)		OT	JP-ABBVIE-20K-087-3369108-00		58 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Gastrointestinal Disorder; General Physical Health Deterioration; Off Label Use	Kaletra			S	Oral	800 / 200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17715835	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-		52 YR	Male	ESP

2020RR-245249

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Paracetamol			S	Oral	1gr Cada 8 Horas		Ohm Lab
	Simvastatina Alter 10 Mg Comprimidos Recubiertos Con Pelicula Efg ...			S	Oral	0-0-1 ()		Not Reported
	Dolquine 200 Mg Comprimidos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17727001	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004251			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Tract Infection Fungal	Hydroxychloroquine			S	Oral	600 Mg, Qd, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia
	Imipenem			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Chlorpromazine			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Urapidil			C		Unk		Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17732418	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245759		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun
	Propofol 2% Inyectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedacion		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)	4 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17741948	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-021386		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742093	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-035046		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Drug Ineffective; Headache; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported

	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral	Unk	Not Reported
	Xeljanz		S	Oral	50 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742136	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231902		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742350	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004645			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742372	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245940		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligrams, Daily		Sun
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	600 Milligrams, Daily		Not Reported
	Effexor L.P. 75 Mg, Gelule A Liberation Prolongee			S	Oral	150 Milligrams, Daily		Not Reported
	Acebutolol (Chlorhydrate D')			C	Oral	400 Milligrams, Daily		Not Reported
	Oxazepam			C	Oral	100 Milligrams, Daily		Not Reported
	Enoxaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))			C	Subcutaneous	4000 International Unit, Daily		Not Reported
	Macrogol 4000			C	Oral	2 Dosage Form, Daily		Not Reported
	Amlodipine			C	Oral	10 Milligrams, Daily		Not Reported
	Chlorhydrate De Clomipramine			C	Oral	150 Milligrams, Monthly		Not Reported
	Zopiclone			C	Oral	7.5 Milligrams, Daily		Not Reported
	Chlorhydrate De Nicardipine			C	Oral	60 Milligrams, Daily		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742377	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245925		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Daily		Sun
	Loxapine Base			S	Oral	155 Milligrams, Daily		Not Reported
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	600 Milligrams, Daily		Not Reported
	Theralene			S	Oral	50 Milligrams, Daily		Not Reported
	Paracetamol			C	Oral	1 Grams, Daily		Not Reported
	Nicopatch 7 Mg/24 H, Dispositif Transdermique De 17,5 Mg/10 Cm^2			C	Transdermal	7 Milligrams, Daily		Not Reported
	Diazepam			C	Oral	10 Milligrams, Daily		Not Reported

	Atorvastatine	C	Oral	40 Milligram, Daily	Not Reported
	Nicotine	C	Oral	12 Milligram, Daily	Not Reported
	Macrogol 4000	C	Oral	Unk	Not Reported
	Nebivolol	C	Oral	7.5 Milligrams, Daily	Not Reported
	Zopiclone	C	Oral	7.5 Milligram, Daily	Not Reported
	Ramipril	C	Oral	1.25 Milligram, Daily	Not Reported
	Akineton	C	Oral	4 Milligram, 1 Minute	Not Reported
	Ezetimibe	C	Oral	10 Milligram, Daily	Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose	C	Oral	75 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration 823 Nos		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Hydromorphone Hcl	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Meloxicam	C			Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742455	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592060		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592094		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-	Actemra			S	Unknown			Not Reported

Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742535	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004726			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S		600 Mg, Bid		Concordia
	Everolimus			C		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232090		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Acetaminophen	C		Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232139		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232163			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742590	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232148			Female	CAN

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

	Meloxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742663	EXPEDITED (15-DAY)		DE, OT	IR-BEH-2020117003			Unknown	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Heart Rate Decreased; Maternal Exposure Timing Unspecified; Maternal Exposure Timing Unspecified	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring
	Oseltamivir			S	Oral			Not Reported
	Ceftriaxone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Oxygen			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Propofol			S	Unknown			Not Reported
	Cisatracurium			S	Unknown			Not Reported
	Red Blood Cells			S	Unknown	Unk		Not Reported
	Red Blood Cells			S	Unknown	Unk		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Plasma, Fresh Frozen			S	Unknown	2 Units		Not Reported
	Norepinephrine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742670	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591905			Male	CAN

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

Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Celecoxib		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Unknown	Powder For Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034928		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, 1 Every 1 Day		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

Prednisone	S	Unknown			Not Reported
Risedronate Sodium	S	Unknown	5 Milligram		Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	500 Milligram		Not Reported
Cyclobenzaprine	C	Unknown	10 Milligram		Not Reported
Desoximetasone	C	Unknown	5 Milligram, 1 Every 1 Day		Not Reported
Leflunomide	C	Unknown			Not Reported
Prednisone Acetate	C	Unknown	5 Milligram, 1 Every 1 Day		Not Reported
Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588925		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591836			Female	CAN

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

Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Rituxan		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Acetylsalicylic Acid		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Gabapentin		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743291	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Orencia			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232132		63 YR	Female	CAN

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

	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743297	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245987		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	200 Mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743508	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591144		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743620	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246009		28 YR	Male	ESP

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

Condition Aggravated; Hepatitis	Azithromycin		S	Oral	500 Mg Dia	Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		S	Oral	400 Mg Dia	Not Reported
	Ceftriaxona		S	Intravenous (not otherwise specified)	2 Gr Dia	Not Reported
	Paracetamol		S	Intravenous (not otherwise specified)	1gr Cada 8 Horas	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743624	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246005		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Daily		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	()		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743627	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246048		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Mg Dia		Sun
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G Dia		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743715	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591858		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743801	EXPEDITED (15-DAY)		HO, OT	CN-ADVANZ PHARMA-202004004658			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Enzyme Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk,		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		One Week After The Patient Started Tiated Hydroxychloroquine		Concordia
	Doxycycline Hyclate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744109	EXPEDITED (15-DAY)		HO, LT	FR-MYLANLABS-2020M1043507		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1 Puis 250 Mg Par Jour		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744126	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590175		62 YR	Male	CAN

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

Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744353	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2020-01836		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Infarction; Intrapartum Haemorrhage; Maternal Exposure During Pregnancy; Pelvic Infection; Placenta Accreta; Post Procedural Complication	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592105		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744998	EXPEDITED (15-DAY)		OT	ES-SA-2020SA115661		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	60 Mg 24 Hours		Sanofi
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745259	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020175440		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug-Induced Liver Injury	Azithromycin			S	Oral	500 Mg, Daily (500 Mg/24h)		Pfizer
	Azithromycin			S				Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily (2gr/24h)		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day (200 Mg/12h)		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745263	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020175443		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745649	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine Besilate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745843	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI-1228870		68 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Sumamed 500 Mg			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Hydroxychloroquine Sulfate 200 Mg			S	Oral	200 Mg,The First Day 1000mg, Then 500mg, Therapy Lasted For 3 Days		Teva
	Midazolam			C				Not Reported
	Lopinavir/Ritonavir			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746040	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230156		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;		Teva

	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid	S	Oral	4 Dosage Forms Daily;	Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746092	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591180		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported
	Remicade			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746179	EXPEDITED (15-DAY)		DE, OT	IR-BEH-2020117006			Unknown	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Heart Rate Decreased; Maternal Exposure Timing Unspecified; Maternal Exposure Timing Unspecified	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring
	Oseltamivir			S	Oral			Not Reported
	Ceftriaxone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Oxygen			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Propofol			S	Unknown			Not Reported
	Cisatracurium			S	Unknown			Not Reported
	Red Blood Cells			S	Unknown	Unk		Not Reported
	Red Blood Cells			S	Unknown	Unk		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Plasma, Fresh Frozen			S	Unknown	2 Units		Not Reported
	Norepinephrine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746206	EXPEDITED (15-DAY)		OT	IR-BEH-2020117007			Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Haemoglobin Decreased; No Adverse Event;	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring

Product Use In Unapproved Indication	Oseltamivir	S	Oral			Not Reported
	Ceftriaxone	S	Oral			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Azithromycin	S	Oral			Not Reported
	Kaletra	S	Oral			Not Reported
	Oxygen	S	Unknown			Not Reported
	Oxygen	S				Not Reported
	Fentanyl	S	Unknown	Unk		Not Reported
	Propofol	S	Unknown	Injection For Intubation		Not Reported
	Propofol	S	Unknown	Infusion For Mechanical Ventilation		Not Reported
	Cisatracurium	S	Unknown			Not Reported
	Red Blood Cells	S	Unknown	1 Unit		Not Reported
	Red Blood Cells	S	Unknown	1 Unit		Not Reported
	Vancomycin	S	Intravenous (not otherwise specified)			Not Reported
	Meropenem	S	Intravenous (not otherwise specified)			Not Reported
	Plasma, Fresh Frozen	S	Unknown	2 Units		Not Reported
	Norepinephrine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746335	EXPEDITED (15-DAY)		DE	US-SLATE RUN PHARMACEUTICALS-20US000055			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Off Label Use	Azithromycin Usp			S	Intravenous (not otherwise specified)	Unk		Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Single		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Steroids			C		Unk		Not Reported

	Steroids			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746449	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Asthenia; Blood Alkaline Phosphatase Increased; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Blood Potassium Decreased; Hypertension; Hypoxia; Lymphopenia; Pneumonia; Respiratory Failure; Serum Ferritin Increased; Type 2 Diabetes Mellitus	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Doxycycline			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ampicillin			C				Not Reported
	Tocilizumab			C				Not Reported
	Ns 1000 Ml			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Benazepril			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Regular Insulin			C				Not Reported
	Neutraphos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746917	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17747361	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1044977		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Qd		Not Reported
	Effexor			S	Oral	150 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Acebutolol			C	Oral	400 Milligram, Qd		Mylan
	Oxazepam			C	Oral	100 Milligram, Qd		Mylan
	Enoxaparine Sodique			C	Subcutaneous	4000 International Unit, Qd		Mylan
	Macrogol 4000			C	Oral	2 Dosage Form, Qd		Mylan
	Amlodipine			C	Oral	10 Milligram, Qd		Mylan
	Clomipramine Hydrochloride			C	Oral	150 Milligram, Monthly		Mylan
	Zopiclone			C	Oral	7.5 Milligram, Qd		Mylan
	Nicardipine Hydrochloride			C	Oral	60 Milligram, Qd		Mylan
	Hydrochlorothiazide			C	Oral	25 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17748223	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Leflunomide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17748237	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012925		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	18253130	DIRECT		OT			50 YR	Male	USA

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

Blood Creatinine Increased; Conjunctivitis; Lung Infiltration	Lopinavir-Ritonavir	S	Oral	400/100 Mg	12 DAY	Not Reported
	Hydroxychloroquine	S	Oral	Dose: 400 Mg, Then 200 Mg Duration: 1 Day, Then 11 Days	1 DAY	Not Reported
	Interferon Alfa-2b	S	Subcutaneous	Frequency: Q48	9 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	11862970	EXPEDITED (15-DAY)		OT	CA-ROCHE-1602815		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 730 Nos		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	12962974	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	12967628	EXPEDITED (15-DAY)		DS	CA-ROCHE-1857523			Female	CAN

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

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13099718	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Atasol With Codeine-Caffeine			C				Not Reported
	Acetaminophen			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C				Not Reported
	Gravol			C				Not Reported
	Levaquin			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13254176	EXPEDITED (15-DAY)		HO	CA-ROCHE-1893244		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13280419	EXPEDITED (15-DAY)		OT	CA-ROCHE-1681465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Actemra			S	Intravenous (not	Therapy Duration: 3 Years		Not Reported

Rheumatoid Arthritis; Therapeutic Response Decreased; Therapeutic Response Decreased; Treatment Failure				otherwise specified)		
	Actemra		S	Intravenous (not otherwise specified)	Therapy Duration: 4 Years	Not Reported
	Enbrel		S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
	Enbrel		S	Subcutaneous	Therapy Duration: 9 Years	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Therapy Duration: 9 Years	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Therapy Duration: 10 Years	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium		S	Subcutaneous	Therapy Duration: 21 Years	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Therapy Duration: 21 Years	Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13300820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902134		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol	Rituxan			S	Intravenous (not			Not Reported

Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Abatacept	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Parenteral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Tofacitinib	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13303889	EXPEDITED (15-DAY)		OT	CA-ROCHE-1900072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal;	Actemra			S	Unknown			Not Reported

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tylenol	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Apo-Hydro	S	Unknown	Not Reported

Apo-Leflunomide	S	Unknown			Not Reported
Apo-Prednisone	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Acetaminophen;Codeine Phosphate	C				Not Reported
Leflunomide	C	Unknown	Therapy Duration: 4 Months		Not Reported
Meloxicam	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Synthroid	C	Unknown			Not Reported
Celebrex	C				Not Reported
Hydromorphone Hcl	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13606666	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941037			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months		Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 2 Years Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 730 Not Otherwise Specified		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported

Enbrel	S	Unknown	Therapy Duration: 731 Not Otherwise Specified	Not Reported
Humira	S	Subcutaneous	Therapy Duration: 5 Months	Not Reported
Humira	S	Unknown		Not Reported
Leflunomide	S	Unknown	Therapy Duration: 5 Months	Not Reported
Leflunomide	S	Unknown	Therapy Duration: 1 Month	Not Reported
Methotrexate	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years	Not Reported
Remicade	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Therapy Duration: 2 Months	Not Reported
Simponi	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Imuran [Azathioprine]	C			Not Reported
Vitamin D3	C	Unknown		Not Reported
Arthrotec	C	Unknown		Not Reported
Clindamycin	C			Not Reported
Cloxacillin	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported

Ergocalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13704329	EXPEDITED (15-DAY)		OT	CA-ROCHE-1955170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Dexamethasone			C				Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C				Not Reported
	Reactine [Cetirizine Hydrochloride]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13915547	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982329		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			C	Oral	Therapy Duration: 365 Days		Not Reported
	Hydroxychloroquine			C	Oral	Therapy Duration-365		Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Leflunomide			C	Oral	Therapy Duration: 549 Days		Not Reported
	Orencia			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13948093	EXPEDITED (15-DAY)		OT	CA-ROCHE-1708212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	4 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13974176	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP017989			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Enbrel	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Ilaris	S	Unknown	Unk		Not Reported
Methotrexate	S	Intra-arterial	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S				Not Reported
Gold	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14152209	EXPEDITED (15-DAY)		HO	CA-ROCHE-2013407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Abnormal; Synovitis	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14242686	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021958		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Unk		Not Reported
	Clonazepam			C	Oral	0.5 Mg, Unk		Not Reported
	Desipramine			C	Unknown	50 Mg, Unk		Not Reported
	Gabapentin			C	Oral	300 Mg, Unk		Not Reported
	Nitroglycerin			C	Unknown			Not Reported

	Rosuvastatin Calcium			C	Oral	20 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14713133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2095769		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringes Single-Use, Preservative-Free Prefilled Synringe; Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Gold			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14849865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114738		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	15322930	EXPEDITED (15-DAY)		DS	CA-ROCHE-2174731		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Prefilled Syringe; Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Not Specified		Not Reported
	Folic Acid			C	Unknown			Not Reported

	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	15449266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191560		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17008473	EXPEDITED (15-DAY)		DS	CA-ROCHE-2454415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthritis; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported

	Indometacin		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Indomethacin [Indometacin]		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17023604	EXPEDITED (15-DAY)		DS	CA-ROCHE-2459894		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Xeljanz	S	Oral		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17042658	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465443		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17233344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509589		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Supeudol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17240953	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019056593		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Kevzara			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Sarilumab			S				Not Reported
	Folic Acid			C				Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17259828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514035		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Penicillin-G			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17412202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000692			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17578035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009106			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Reactin /00884302/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17580690	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023759		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17662281	EXPEDITED (15-DAY)			FR-ADVANZ PHARMA-202003002582			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17665011	NON-EXPEDITED			US-PFIZER INC-2020152441		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17670925	EXPEDITED (15-DAY)		DE, OT	ES-CIPLA LTD.-2020ES02594			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Cipla
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Per Day		Not Reported
	Azitromicina			S	Oral	500 Milligram, Per Day		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid, (12 H)		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Unknown	Unk		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Per Day		Not Reported
	Prednisona			C	Oral	20 Milligram, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17671057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009843			Female	CAN

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

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, B.I.Wk.	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Unk (Cyclical)	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, Unk Cyclical	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, T.I.W	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Q.O.Wk.	Apotex
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, B.I.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.O.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17689640	EXPEDITED (15-DAY)		DE, HO, OT	SK-BAXTER-2020BAX007949		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc	Endoxan 1000 Mg Prasok Na Injekcny Roztok			S	Unknown	Unk		Baxter
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Azathioprine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Cyclosporine A		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Belimumab		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17699793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586666		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Piroxicam			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Teva Mycophenolate	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17713157	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020161842		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Drug Ineffective; Pneumonia; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17715830	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245242		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17729805	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020171215		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer
	Azithromycin			S				Pfizer
	Dolquine			S	Other	400 Mg, Daily (Via Nasogastric Tube)		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17732183	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590384		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591079		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

					otherwise specified)					
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592025		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748502	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-021696		43 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748521	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022017		57 YR	Female	ESP

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

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Milligram, Dia	Aurobindo
	Roactemra	S	Intravenous (not otherwise specified)	600 Milligram	Not Reported
	Roactemra	S			Not Reported
	Lopinavir;Ritonavir	S	Oral	2 U, Two Times A Day	Not Reported
	Lopinavir;Ritonavir	S			Not Reported
	Hidroxicloroquina	S	Oral	400 Milligram, Dia	Not Reported
	Hidroxicloroquina	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748548	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050103			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Qd		Zydus Pharm
	Plaquenil Sulfate			S	Oral	800 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748701	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-022018		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Roactemra			C	Intravenous (not otherwise specified)	600 Milligram,1 Total		Not Reported
	Roactemra			C				Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748835	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591229		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749054	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749117	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592495			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749294	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593188			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749626	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590880			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749765	EXPEDITED (15-DAY)		OT	NVSC2020IR111437		24 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749788	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1230789		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	800 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749846	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202004004835			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S		7 Little Pills		Concordia
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590257		53 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750016	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2590470		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-	Actemra			S	Unknown			Not Reported

Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Minocycline	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

	Orencia	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750116	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2020-ES-1230679		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Pneumonia Escherichia; Ventricular Tachycardia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750118	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230310		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

Hepatitis	Hidroxicloroquina (2143a)	S				Teva
	Azitromicina (7019a)	S	Oral	500 Milligram Daily;		Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750156	EXPEDITED (15-DAY)		HO	SE-ACCORD-180870		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	Intentional Overdose		Accord
	Prednisolone			S	Oral	10-15 St, Intentional Overdose		Not Reported
	Plaquenil			S	Oral	10-15 St, Intentional Overdose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750216	NON-EXPEDITED			US-PFIZER INC-2020180158		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Joint Swelling; Peripheral Swelling	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750441	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245841		51 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Glomerulonephritis Membranous	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Prednisolone			C	Unknown	Unk (40 Mg/ Day Of		Not Reported

Prednisolone With Gradual Taper To 5 Mg/Day And Maintained)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750591	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592747		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	94.0 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750608	DIRECT	Y				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunodeficiency; Vomiting	Hydroxychloriquine		Y	S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750700	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231666		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sarilumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750721	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246167		73 YR	Male	ESP

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

Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin		S	Oral	500 Mg Dia	Sun
	Ertapenem (2881a)		S	Intravenous (not otherwise specified)	1 G Dia	Not Reported
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg,...		S	Intravenous (not otherwise specified)	C/24 H	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		S	Oral	400 Mg Dia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750989	EXPEDITED (15-DAY)		OT	CH-TEVA-2020-CH-1231349		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia;	Doxycycline			S	Oral			Actavis

Thrombocytopenia; Thrombotic Microangiopathy	Azithromycin		S	Oral		Unknown
	Amoxicillin And Clavulanate Potassium		S	Intravenous drip		Teva
	Plaquenil		S	Oral	800 Mg 22-23/03, 400 Mg 24-26/03, 600 Mg 26-30/03	Not Reported
	Enoxaparin		S	Subcutaneous		Not Reported
	Durogesic		S	Transdermal	Patch 25 Mcg/H : 1 Every 3 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751040	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591815		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751253	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591867		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231392			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Morphine Sulfate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Aclasta			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plantago Afra	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Asa	C	Unknown	81 Milligram Daily;	Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	2000 Iu (International Unit) Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lipitor	C	Unknown	10 Milligram Daily;	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751521	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231640		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751548	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020178177		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751585	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020180060		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			S	Oral	2 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751680	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006814		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Cyclosporine	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.O.Wk.	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	75 Mg, Q.M.T.	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.O.Wk.	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Endocervical	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported

Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Unknown	2 Df, Qd		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Arava	C	Oral	20 Mg, Qd		Not Reported
Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Risedronate	C	Oral	35 Mg, Q.Wk.		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz Xr	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751718	EXPEDITED (15-DAY)		OT	NVSC2020FR120436		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Plaquenil			S	Oral	1 Df, Qd		Not Reported
	Noxafil			S	Oral	300 Mg, Qd		Not Reported
	Zithromax			S	Oral	250 Mg, Qd		Not Reported
	Ursodesoxycholic Acid			C	Unknown	Unk		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Ethambutol			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Aldactone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751882	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020178687		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Ertapenem			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	C/24h		Not Reported
	Dolquine			S	Oral	400 Mg, Daily		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751896	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020178145		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752072	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050251			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram		Zydus Pharm
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Milligram		Not Reported
	Rocephine			S	Oral	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752139	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020178148		60 YR	Female	FRA

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

Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax	S	Oral	250 Mg, 1x/Day	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752148	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA119135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Phenylephrine			S	Unknown	Unk		Novartis
	Benzalkonium Chloride			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride		Y	S	Unknown	Unk		Not Reported
	Phenylephrine Hydrochloride			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Oral	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Boric Acid			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Disodium Edetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Mg, Qw		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Qmo		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rho D Immune Globulin			S	Unknown	Unk		Not Reported

Simponi	S	Unknown	Unk		Not Reported
Sodium Borate	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Unknown	10 Mg, Q2w		Not Reported
Tofacitinib Citrate	S	Unknown	10 Mg, Q2w		Not Reported
Tofacitinib Citrate	S	Subcutaneous	10 Mg, Q2w		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Ibuprofen	C	Unknown	Unk		Not Reported
Lipitor	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752280	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Ill-Defined Disorder; Malaise; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592876		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752382	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2020-AMRX-01266		61 YR	Female	USA

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

Astigmatism; Cornea Verticillata	Hydroxychloroquine Sulfate		S	Unknown	600 Milligram, Bid (1200mg, 21.9 Mg/Kg/Day)	Amneal
	Everolimus		C	Unknown	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752490	EXPEDITED (15-DAY)		DS, HO, LT, OT	NVSC2020SK103006		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Cefotaxime			S	Unknown	Unk		Not Reported
	Cefotaxime			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Novartis
	Omeprazole			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported
	Acetaminophen (Paracetamol)			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Fluconazole			S	Unknown	Unk		Not Reported
	Penicillin G Benzathine			S	Unknown	Unk		Not Reported
	Vitamin K Nos			S	Unknown	Unk		Not Reported
	Bisulepin			S	Unknown	Unk		Not Reported
	Nadroparin Calcium			S	Unknown	Unk		Not Reported
	Etamsylate			S	Unknown	Unk		Not Reported
	Privigen			S	Unknown	Unk		Not Reported
	Flebogamma Dif			S	Unknown	Unk		Not Reported
	Potassium Chloride			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

Vitamin B Complex	S	Unknown	Unk		Not Reported
Albumin	S	Unknown	Unk		Not Reported
Ornidazole	S	Unknown	Unk		Not Reported
Magnesium Lactate	S	Unknown	Unk		Not Reported
Methylprednisolone	S	Unknown	Unk		Not Reported
Methylprednisolone	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Amcal Hydrocortisone	S	Unknown	Unk		Not Reported
Vulmizolin	S	Unknown	Unk		Not Reported
Aminomethylbenzoic Acid	S	Unknown	Unk		Not Reported
Cc Vital Vitamin D [Cholecalciferol]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752805	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045208		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Paracetamol			S	Intravenous (not otherwise specified)	1gr Cada 8 Horas		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752820	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045211		63 YR	Male	ESP

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

Condition Aggravated; Hepatitis	Azithromycin		S	Oral	500 Mg Dia	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Milligram, Total	Mylan
	Dolquine		S	Oral	400 Mg Dia	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752855	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1045224		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Quetiapine			S	Oral	25 Milligram, Qd		Not Reported
	Risperidone			S	Oral	1 Milligram, Qd		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Bid		Mylan
	Levofloxacino /01278901/			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Mylan
	Furosemida /00032601/			C	Oral	40 Milligram, Qd		Mylan
	Losartan			C	Oral	50 Milligram, Qd		Mylan
	Clindamicina /00166002/			C	Intravenous (not otherwise specified)	600 Milligram, Q6h		Mylan
	Lorazepam			C	Oral	1 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752857	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1045184		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Lovenox			C	Oral	Unk		Mylan
	Paracetamol			C	Oral	Unk		Mylan

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752859	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045179		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)	Cada 8 Horas		Not Reported
	Amoxicillin/Clavulanic Acid			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754146	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012923		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Amoxicillin Sodium;Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported
	Bacillus Calmette-Guerin Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Bacillus Calmette-Guerin Bcg	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754149	EXPEDITED (15-DAY)		LT	CA-BAUSCH-BL-2020-012932		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported

Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C		Not Reported
	Lyrica	C		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754163	EXPEDITED (15-DAY)		DE, LT	CA-BAUSCH-BL-2020-012936		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Actemra			S	Unknown	Dosage Form Not Specified		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Leflunomida			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754170	EXPEDITED (15-DAY)		DE	ES-BAUSCH-BL-2020-012998		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sudden Death	Salbutamol (2297a)			S	Respiratory (inhalation)			Bausch And Lomb
	Dolquine			S	Oral	30 Tablets		Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)			Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina (7019a)			S	Oral			Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)			Not Reported
	Cefotaxima (3840a)			C	Intravenous drip			Not Reported

	Midazolam (2256a)	C	Intravenous drip	Not Reported
	Enoxaparina Sodica (2482so)	C	Subcutaneous	Not Reported
	Tocilizumab (8289a)	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754176	EXPEDITED (15-DAY)		HO, LT	CA-BAUSCH-BL-2020-012937			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Oxycodone			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Marijuana			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754512	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230680		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1gr Every 8 Hours		Not Reported

	Metamizol (111a)		S	Intravenous (not otherwise specified)	2gr Every 6 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594194		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	18246578	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Infection; Oxygen Consumption Increased	Lopinavir-Ritonavir			S	Oral	Dose: 200/50: Bid (2-0-2)/ Po		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	18251821	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	Other Dose:500mg-250mg;	3 DAY	Not Reported
	Hydroxychloroquine			S	Oral	Other Dose:400mg-200df;	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	18251959	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Oral	Other Dose:500mg/250mg;	4 DAY	Not Reported
	Hydroxychloroquine			S	Oral	Other Dose:400mg/200mg;	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	11105334	EXPEDITED (15-DAY)		OT	CA-ROCHE-1574386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous	Duration : 1095 Days	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Solution For Injection	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Synthroid	C		Not Reported
Lasix [Furosemide]	C	Unknown	Not Reported
Enablex [Darifenacin Hydrobromide]	C		Not Reported
Ativan	C		Not Reported
Loperamide	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Vagifem	C	Vaginal	Not Reported
Cortisone	C	Intramuscular	Not Reported
Dilaudid	C	Unknown	Not Reported
Abatacept	C		Not Reported
Leflunomide	C		Not Reported
Kineret	C		Not Reported
Furosemide	C	Unknown	Not Reported
Diphenhydramine Hydrochloride	C		Not Reported
Darifenacin Hydrobromide	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Oxyneo	C	Unknown	Not Reported
Trimethoprim	C		Not Reported
Restasis	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C		Not Reported
Kadian	C	Unknown	Not Reported
Codeine	C		Not Reported
Acetaminophen	C		Not Reported
Anakinra	C		Not Reported
Desoximetasone	C		Not Reported
Dexamethasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12098241	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712937			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Dose Reduced		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Frequency: Every 1 Day; Therapy Duration: 4 Months, Stopped Due To Nausea,Vomiting, Intolerance		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12810481	EXPEDITED (15-DAY)		OT	CA-ROCHE-1837479		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Pain	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Methotrexate Sodium	S	Oral			Not Reported
Lyrica	S	Oral			Not Reported
Leflunomide	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Tylenol	C	Unknown	As Required		Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12923504	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1632295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Pre-Filled Syringe		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12981186	EXPEDITED (15-DAY)		OT	CA-ROCHE-1853913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Subcutaneous	Single Use, Solution		Not Reported

			Subcutaneous		
Methotrexate		S	Subcutaneous		Not Reported
Methotrexate		S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
Methotrexate		S	Unknown		Not Reported
Apo-Leflunomide		S	Unknown		Not Reported
Apo-Leflunomide		S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol		S	Unknown		Not Reported
Hydroxychloroquine		S	Unknown		Not Reported
Hydroxychloroquine Sulfate		S	Unknown		Not Reported
Leflunomide		S	Unknown		Not Reported
Leflunomide		S	Unknown		Not Reported
Rituximab		S	Unknown		Not Reported
Arthrotec		C	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Therapy Duration: 8 Years	Not Reported
Imuran [Azathioprine]		C	Unknown		Not Reported
Vitamin D3		C	Oral		Not Reported
Azathioprine		C			Not Reported
Ergocalciferol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13099777	EXPEDITED (15-DAY)		OT	CA-ROCHE-1595142		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Infection; Loss Of Personal Independence In Daily Activities; Mobility	Rituxan			S	Intravenous (not otherwise specified)	Cyclical, Therapy Duration: 8 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Went Up To 25 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported

Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira	S	Subcutaneous	Therapy Duration: 7 Months	Not Reported
	Arava	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown	Did Not Work Therapy Duration: 3 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 3 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Actonel	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13099811	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876558			Female	CAN

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

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13116927	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878962		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13136489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882213		43 YR	Female	CAN

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

	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13233237	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893773		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13315469	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808080		64 YR	Female	CAN

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

Treatment Failure	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cortisone	C	Unknown		Not Reported
	Cyclobenzaprine	C	Unknown	1/2 Tablet As Needed	Not Reported
	Tylenol	C	Unknown	As Needed	Not Reported
	Prednisone Acetate	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13735259	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1356654		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Pressure Decreased; Blood Pressure Fluctuation; Blood Pressure Increased; Body Temperature Decreased; Cataract; Chills; Colitis Microscopic; Cough; Diarrhoea; Ear Pruritus; Fatigue; Headache; Hypertension; Hypotension; Hypotension; Hypotension; Malaise; Nasal Congestion; Nasopharyngitis; Nasopharyngitis; Oral Pruritus; Perforated Ulcer; Procedural Pain; Pyrexia; Renal Disorder; Single Functional Kidney; Sleep Disorder; Throat Irritation;	Rituxan			S	Intravenous (not otherwise specified)	Form Strength: 500 Mg/50 Ml Most Recent Dose Was On 19/Jun/2014 Most Recent Rituxan Dose On 18/Jan/2		Not Reported
	Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Stopped Approx. Aug 2013		Not Reported
	Prednisone			S	Unknown	Stopped Approx. Jan 2013		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Pms-Sulfasalazine			C				Not Reported
	Eltroxin			C				Not Reported
	Gabapentin			C				Not Reported

Weight Decreased; Weight Increased; White Blood Cell Count Decreased	Hydromorphone	C		Not Reported
	Lansoprazole	C		Not Reported
	Lorazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13952660	EXPEDITED (15-DAY)		OT	CA-ROCHE-1990184		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15041745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2142618		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

					otherwise specified)					
	Apo-Leflunomide			S	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15260270	EXPEDITED (15-DAY)		HO	CA-ROCHE-2164477		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15411424	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186685		76 YR	Female	CAN

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

Arthropathy; Blood Creatinine Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Knee Arthroplasty; Limb Discomfort; Musculoskeletal Discomfort; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15417133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188024		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	16387997	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029784		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Celecoxib Capsules			S	Oral	200 Milligram, Once A Day		Aurobindo
	Levofloxacin Tablet			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Intravenous (not otherwise specified)	5 Milligram		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Once A Day		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide Sandoz			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Meperidine Hydrochloride			S	Unknown	Unk		Not Reported
	Meperidine Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported
	Norfloxacin			S	Unknown	400 Milligram		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

Prednisone	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Bisoprolol	S	Unknown	Unk		Not Reported
Erythro Base	S	Unknown	Unk		Not Reported
Act Diclo Miso	S	Unknown	Unk		Not Reported
Apo-Bisoprolol	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Metronidazole	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17024875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461902			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17025673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17088391	EXPEDITED (15-DAY)		DS	CA-ROCHE-2475266		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported

Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Colchicine	C	Oral	Not Reported
	Dexilant	C		Not Reported
	Febuxostat	C		Not Reported
	Folic Acid	C		Not Reported
	Gravol	C		Not Reported
	Mogadon	C	Oral	Not Reported
	Nitrazepam	C	Unknown	Not Reported
	Oxycodone	C		Not Reported
	Prednisone	C		Not Reported
	Uloric	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17235421	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508675		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arthrotec			C	Oral			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17279295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17338159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530847		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported

	Folic Acid	C	Unknown	Not Reported
	Ketorolac	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17358684	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Actemra			S	Intratumor			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17360983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531687		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Naproxen	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Rituxan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17399434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539634		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	8.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported

Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Folic Acid	C	Unknown	Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Naprosyn [Naproxen]	C		Not Reported
	Oxycontin	C		Not Reported
	Oxyneo	C		Not Reported
	Diphenhydramine Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17422945	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010439		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17423321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542982		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17465564	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025776		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Prednisone			C	Oral	5 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17690932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17715901	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1228878		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg, Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)			Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Mg, Metoclopramida (1958a)		Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)	20 Mcg		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous			Not Reported
	Cefotaxima (3840a)			C	Intravenous drip	4gram		Not Reported
	Midazolam (2256a)			C	Intravenous drip	100 Mg		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17722969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590358			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17743628	EXPEDITED (15-DAY)		CA	DE-UCBSA-2020017797			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Talipes	Certolizumab Pegol			S	Transplacental	Unknown Dose		Not Reported
	Prednisolone			S	Transplacental	Unknown Dose		Not Reported
	Hydroxychloroquine			S	Transplacental	Unknown Dose		Not Reported
	Sulfasalazine			S	Transplacental	Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753395	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-021940		54 YR	Male	FRA

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

Hyperkalaemia	Perindopril		S	Oral	Unk	Aurobindo
	Plaquenil		S	Oral	600 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753415	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-021808		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day		Aurobindo
	Kaletra			S	Oral	4 Dosage Form, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753627	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022319		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753673	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022323		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Tocilizumab			S				Not Reported

	Hydroxychloroquine		S	Oral	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754072	EXPEDITED (15-DAY)		HO, LT	SI-TEVA-2020-SI-1233311		48 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Thrombocytopenia	Hydroxychloroquine Sulfate 200 Mg			S	Oral	200 Mg		Teva
	Kaletra (80 Mg + 20 Mg) / Ml			S	Oral	(80mg+20mg)/Ml Oral Solution, Dose 400mg/100 Mg, 1 Dosage Forms		Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Esmeron			C				Not Reported
	Metoclopramid			C				Not Reported
	Analgin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754382	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004842			Unknown	USA

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

Blood Thyroid Stimulating Hormone Decreased; Depersonalisation/Dereali sation Disorder; Disturbance In Attention; Dyspnoea; Fatigue; Heart Rate Increased; Inflammation; Malaise; Somnolence; Weight Increased	Hydroxychloroquine	S		Unk	Concordia
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754566	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Endocervical			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Naproxen	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Rituxan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754573	EXPEDITED (15-DAY)		DS	CA-ROCHE-2593227			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	92.0 Days	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754657	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591253		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	944		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Myochrysine		S	Intramuscular		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	365	Not Reported
	Rituxan		S	Intravenous drip		Not Reported
	Rituximab		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593494			Female	CAN

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

Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593515			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Dorzolamide;Timolol			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754972	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010524			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754993	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1230791		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Paracetamol (12a)			S	Oral	3 Gram Daily;		Not Reported
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	75 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755011	EXPEDITED (15-DAY)		DE	NVSC2020IR111441		9 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Fungal Infection	Hydroxychloroquine			S	Oral			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755019	EXPEDITED (15-DAY)		OT	NVSC2020US121646		61 YR	Female	USA

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

Cornea Verticillata	Hydroxychloroquine Sulfate Tablets Usp	S	Unknown	600 Mg, Bid		Novartis
	Everolimus	S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755116	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230945		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755117	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1231564		43 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Paracetamol (12a)			S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592731		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury;	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Humira		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Leflunomide		S	Unknown	Therapy Duration: 6.0 Years	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590945		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755361	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1231568		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Daily		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500mg Daily		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Anakinra (2699a)			S	Subcutaneous	100 Mg		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Daily		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593389		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Cimzia	S	Subcutaneous		Not Reported
	Aspirin [Acetylsalicylic Acid]	C			Not Reported
	Cymbalta	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755414	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593751		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594111		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	84.0 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	171.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755896	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594375		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Solution Intravenous		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756170	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003663			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756177	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1045121		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ambisome /00057501/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400mg/24h		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756292	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFM-2020-13035			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Propranolol			S	Oral	20 Mg, Every 12 Hours		Pierre Fabre Medicament
	Laroxyl			S	Oral	15 Gtt Daily		Not Reported
	Plaquenil			S	Oral	400 Mg, Every 12 Hours		Not Reported
	Zithromax			S	Oral			Not Reported
	Paracetamol			C	Oral	Prn		Not Reported
	Pantoprazole			C	Oral	20 Mg Daily		Not Reported
	Oxygen			C	Respiratory	1 L Every Min		Not Reported

(inhalation)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591074			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Reactine [Cetirizine			S	Unknown			Not Reported

	Hydrochloride]			
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756579	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231653		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756591	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231662		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition	Codeine			S	Unknown			Not Reported

Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592410		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 198.0 Days		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 156.0 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Prednisone		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756749	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756797	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2594249		48 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756818	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1045233		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Azithromycine Sandoz /00944304/			S	Oral	250 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756918	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported

Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Rituximab	S	Intravenous drip	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756998	EXPEDITED (15-DAY)		LT	CA-BAUSCH-BL-2020-013031		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity	Minocycline Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported

Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Salfasalazine	S	Unknown	Not Reported
	Salfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593721		62 YR	Female	CAN

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

Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Months	Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	Therapy Duration: 4.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757227	EXPEDITED (15-DAY)		OT	ES-SA-2020SA118630		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulpiride			S	Oral	50 Mg Every 8 Hours		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg Day		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757238	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1231627		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate	C	Unknown		Not Reported

	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231621		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757245	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757282	EXPEDITED (15-DAY)		OT	CA-SA-2020SA117632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Tofacitinib Citrate	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757316	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231661			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Colectomy; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure; Treatment Failure	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757399	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1231650		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757479	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Macular Degeneration; Pancreatitis	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232100		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Actonel			S	Oral			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Oral	3.2143 Milligram Daily;		Not Reported
Novo-Rythro	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Bupropion	C	Unknown			Not Reported
Cannabis Sativa	C	Unknown			Not Reported
Celebrex	C	Unknown	400 Milligram Daily;		Not Reported
Celebrex	C	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Hydroxychloroquine	C	Oral	400 Milligram Daily;		Not Reported
Wellbutrin	C	Unknown			Not Reported
Wellbutrin	C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757490	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232011		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	10 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757559	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020179134			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Morphine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757730	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395337-00		68 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Roactemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757800	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3395439-00		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757860	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395468-00		70 YR	Male	ITA

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

Hypertransaminasaemia; Off Label Use	Kaletra	S	Oral		Not Reported
	Zitromax Avium	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758020	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231932			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594137		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated;	Actemra			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	4.0 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758595	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593996		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758709	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3392070-00		82 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S	Oral			Not Reported
	Erythromycin			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil	S	Oral		Not Reported
	Actemra	C	Intravenous drip		Not Reported
	Tazobac	C		2.0gr / 0.25mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758863	EXPEDITED (15-DAY)		OT	RO-AUROBINDO-AUR-APL-2020-024107			Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Rupture; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Zinc			S	Unknown	Unk		Not Reported
	Vitamin C			S	Unknown	Unk		Not Reported
	Algozone			S	Unknown	Unk		Not Reported
	Norvir			S	Oral	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Lopinavir			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17759741	DIRECT	Y	DE			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Fibrinogen Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Right; Covid-19 Pneumonia; Dyspnoea; Electrocardiogram Qt Prolonged; Fibrin D Dimer	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Ceftriaxone			C				Not Reported
	Vancomycin			C				Not Reported
	Azithromycin			C				Not Reported
	Tocilizumab			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Enoxaparin			C				Not Reported
	Ipratropium			C				Not Reported
	Losartan			C				Not Reported
	Oxymetazoline			C				Not Reported

Increased; Hypertension; Hypokalaemia; Hypoxia; Leukocytosis; Myocardial Infarction; Oedema Peripheral; Sars-Cov-2 Test Positive; Serum Ferritin Increased; Sinus Tachycardia	Kcl	C		Not Reported
	Propofol	C		Not Reported
	Norepinephrine	C		Not Reported
	Oseltamivir	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	11820435	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675314		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Does Not Tolerate 1 G Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	11999096	EXPEDITED (15-DAY)		DS	CA-ROCHE-1703918		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Anakinra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Remicade			S	Intravenous (not	Therapy Duration: 5 Years		Not Reported

				otherwise specified)	
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine		C		Not Reported
	Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	12852770	EXPEDITED (15-DAY)		LT, OT	CA-ROCHE-1695185		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral	4 Pills		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13015516	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865715		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Therapy Duratin: 6 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Gp2013	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Subcutaneous		Not Reported
Leflunomide	C	Unknown	Therapy Duration: 6 Months	Not Reported
Xeljanz	C	Oral		Not Reported
Celebrex	C			Not Reported
Diclofenac	C			Not Reported
Lyrica	C			Not Reported
Sulfasalazine	C			Not Reported
Valsartan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13053281	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870963			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Adalimumab	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Folic Acid	C	Oral	Not Reported
Pantoprazole	C		Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Oral	Not Reported
Tenofovir Disoproxil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13067695	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Fatigue; Pulmonary Mass; Rheumatoid Nodule; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13201712	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Restasis			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13253859	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894972		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 365.0 Nos		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 19.0 Year(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 19.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Therapy Duration: 365.0	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13262211	EXPEDITED (15-DAY)		OT	CA-ROCHE-1662402		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13704441	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955227			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S			Not Reported
Marijuana	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Oxycodone	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	14678468	EXPEDITED (15-DAY)		OT	CA-ROCHE-2089917		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Arthritis	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	14950745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2131646		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15275955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167429		54 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15393834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184304		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Risedronate Sodium	C		Not Reported
	Actonel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15438740	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15944441	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA034910		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Clopidogrel Bisulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Furosemide			S	Unknown			Sanofi
	Famotidine			S	Unknown	Unk Unk, Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Doxycycline			S	Unknown	Unk Unk, Unk		Not Reported
	Trandolapril			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Nifedipine			S	Unknown	Unk Unk, Unk		Not Reported
	Loperamide			S	Unknown	Unk Unk, Unk		Not Reported
	Ambien			S	Unknown	Unk Unk, Unk		Sanofi
	Gabapentin			S	Unknown	Unk Unk, Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk Unk, Unk		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk Unk, Unk		Not Reported
	Potassium			S	Unknown	Unk Unk, Unk		Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk Unk, Unk		Sanofi
	Metoclopramide Hydrochloride			S		Unk Unk, Unk		Not Reported
	Trazodone Hydrochloride			S		Unk Unk, Unk		Not Reported
	Isosorbide Mononitrate			S		Unk Unk, Unk		Not Reported
	Victoza			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qod		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S				Not Reported
	Flomax [Morniflumate]			S	Unknown	Unk Unk, Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	16451752	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019048692		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S		Unk		Pfizer
	Pamidronate Disodium			S		Unk		Pfizer
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Doxycycline			S	Unknown	Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	Unk		Pfizer
	Stelara			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Tenoxicam			S	Unknown	Unk		Not Reported
	Bromocriptine			S		Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Mercaptopurine			C				Not Reported
	Methylprednisolone			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17024068	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17108802	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-063176			Female	CAN

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

	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljan	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17240218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509529		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Product Effect Decreased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Varenicline Tartrate	S	Oral	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Oral	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Naproxen	C	Unknown	Not Reported
	Naproxen	C	Oral	Not Reported
	Naproxen	C	Oral	Not Reported
	Oxycodone Hydrochloride	C		Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Valtrex	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17245971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512719			Female	CAN

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

Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17259394	EXPEDITED (15-DAY)		HO	CA-ROCHE-2518182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17260727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515953		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Synovitis; X-Ray Abnormal	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Penicillin-G	S	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Calcium	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17443400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552179		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17484426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559700		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17662183	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002382			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hallucination, Visual; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia
	Temesta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17663375	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-018165		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Once A Day		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline Tartrate Renaudin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Once A Day		Not Reported
	Transipeg			C	Oral	Unk		Not Reported
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Nimbex			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Effexor			C	Oral	Unk		Not Reported
	Ultibro Breezhaler			C	Respiratory (inhalation)	Unk		Not Reported
	Seresta			C	Oral	Unk		Not Reported
	Rocephine			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17670319	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003746		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Enoxaparin Sodium			C	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Ceftriaxone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17707946	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202004003809			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17717548	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586707		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased;	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17721358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588511			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Folic Acid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17736281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17744178	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436844			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Plaquenil /00072602/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17744182	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200436802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17744192	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200436812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17745328	EXPEDITED (15-DAY)			CH-PFIZER INC-2020175487		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Zithromax			S	Oral	500 Mg		Pfizer
	Piperacillin/Tazobactam			S	Intravenous drip	4.5 G		Pfizer
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Intravenous drip	1.2 G		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	800 Mg (In Total)	Not Reported
Kaletra	S	Oral	400 Mg	Not Reported
Kaletra	S	Oral	400 Mg	Not Reported
Clexane	S	Subcutaneous	40 Mg	Not Reported
Clexane	S	Subcutaneous	40 Mg	Not Reported
Clexane	S	Subcutaneous	Unk	Not Reported
Clexane	S	Subcutaneous	40 Mg	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	1 Mg (Max 3x/Day ; As Necessary)	Not Reported
Ipramol	C		Unk	Not Reported
Temesta [Lorazepam]	C		Unk	Not Reported
Tavanic	C		Unk	Not Reported
Atracurium	C		Unk	Not Reported
Fentanyl	C		Unk	Not Reported
Dormicum [Midazolam Maleate]	C		Unk	Not Reported
Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C		Unk	Not Reported
Colistin	C		Unk	Not Reported
Torasemide	C		Unk	Not Reported
Potassium	C		Unk	Not Reported
Benerva	C		Unk	Not Reported
Heparin	C		Unk	Not Reported
Solu-Medrol	C		Unk	Not Reported
Novorapid	C		Unk	Not Reported
Relistor	C		Unk	Not Reported
Novasource Gi Control	C		Unk	Not Reported
Ventoline [Salbutamol]	C		Unk (As Necessary)	Not Reported
Movicol	C		Unk (As Necessary)	Not Reported
Tobramycin	C		Unk	Not Reported

	Amphotericin B	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17747516	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cortisone Acetate			S		25 Mg		Not Reported
	Arava			S	Oral	20 Mg		Sanofi
	Cetirizine Hydrochloride			S		25 Mg		Not Reported
	Cetirizine Hydrochloride			S		10 Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Hydrocortisone Acetate			S	Subcutaneous			Sanofi
	Methotrexate			S	Oral	Unk Unk, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Pseudoephedrine Hydrochloride			S				Sanofi
	Sarilumab			S				Sanofi
	Sulfasalazine			S	Oral	1 Df, 1 Gram		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi
	Topicort			S	Subcutaneous			Sanofi
	Acetaminophen			S				Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Prednisone			S				Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	20 Mg, Qw		Not Reported

Fosamax	S	Oral	Unk		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Golimumab	S				Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Methotrexate Sodium	S	Oral	25 Mg		Not Reported
Orencia	S	Subcutaneous			Not Reported
Phthalylsulfathiazole	S		Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S		Unk		Not Reported
Sulfathalidine	S				Not Reported
Xeljanz	S		5 Mg, Bid		Not Reported
Salazopyrina	C		Unk		Not Reported
Tofacitinib Citrate	C		Unk		Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17758660	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3390697-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Back Pain; Body Height Decreased; C-Reactive Protein Decreased; Deep Vein Thrombosis; Depression; Drug Ineffective; Drug Ineffective; Emotional Distress; Emotional Distress; Fatigue; Foot	Humira			S	Subcutaneous			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Fracture; Malaise; Osteoporosis; Pelvic Fracture; Pruritus Allergic; Psoriasis; Psoriatic Arthropathy; Quality Of Life Decreased; Rheumatoid Arthritis; Sensitivity To Weather Change; Spinal Fracture	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Methotrexate Sodium	C	Oral	Not Reported
	Warfarin	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Vioxx	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17758765	EXPEDITED (15-DAY)		HO, OT	IT-ADVANZ PHARMA-202004004915			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17758976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594187		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759106	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2593615		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593284		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Joint Swelling; Laboratory Test Abnormal;	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759190	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592797		36 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594201		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759235	EXPEDITED (15-DAY)		OT	ES-SA-2020SA118599		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759255	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594261		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder	Actemra			S	Intravenous (not			Not Reported

Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia				otherwise specified)	
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592749		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Diovan			C				Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C				Not Reported
	Sertraline			C	Unknown			Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759454	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202004004823			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Haemodynamic Instability;	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

Off Label Use; Renal Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759495	EXPEDITED (15-DAY)		HO, OT	ALC2020CA003397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Phenylephrine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg 1 Every 1 Months		Not Reported
	Arava			S	Unknown	20.0 Mg		Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown	Solution Subcutaneous (Single-Use Prefilled Syringe)		Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40.0 Mg 1 Every 1 Week		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, Bid		Not Reported
	Methotrexate			S	Oral	15.0 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid		Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported

Rituximab	S	Unknown			Not Reported
Simponi	S	Unknown			Not Reported
Sodium Borate	S	Unknown			Not Reported
Sulfasalazine	S	Oral			Not Reported
Tofacitinib Citrate	S	Unknown	10.0 Mg, Q2w		Not Reported
Tofacitinib Citrate	S	Unknown	10.0 Mg, Q2w		Not Reported
Tofacitinib Citrate	S	Subcutaneous	10.0 Mg, Q2w		Not Reported
Prednisone	C	Unknown			Not Reported
Celebrex	C	Oral	400.0 Mg		Not Reported
Ibuprofen	C	Oral	400.0 Mg		Not Reported
Lipitor	C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759506	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594292			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759507	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Rituxan			S	Intravenous (not			Not Reported

Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling				otherwise specified)	
	Gold		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Celebrex		C	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Frequency: Cyclical		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Indomethacin [Indometacin]	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593767			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759960	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592727		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594885		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760032	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593250		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

Acetaminophen	C		Not Reported
Cetirizine Hydrochloride	C		Not Reported
Desoximetasone	C		Not Reported
Dexamethasone	C		Not Reported
Gabapentin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760116	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Measured Potency Issue; Therapy Non-Responder	Hydroxychloroquine Sulfate			S				Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760294	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA116702		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	60 Mg, Q12h		Sanofi
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Qd For 6 Days Followed By 10 Mg Day X 5 Days		Not Reported
	Dexamethasone			S				Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Azithromycin			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, 1x		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760385	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS		61 YR	Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata; Off Label Use	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	1200 Milligram (21.9 Mg/Kg) High Dose		Lupin
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported
	Everolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760413	EXPEDITED (15-DAY)		DE, OT	ES-VELOXIS PHARMACEUTICALS-2020VELES-000434		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Envarsus			S	Oral	Unk		Chiesi
	Lopinavir + Ritonavir			S	Oral	2 Df, Q12h		Not Reported
	Azitromicina			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Not Reported
	Levofloxacino [Levofloxacin]			S	Endocervical	Unk		Not Reported
	Prednisona			C	Oral	20 Milligram, Qd		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Endocervical	Unk		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760655	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760679	EXPEDITED (15-DAY)		OT	NVSC2020DE122948			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Roactemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760691	EXPEDITED (15-DAY)		DS	CA-ROCHE-2590101		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indocid [Indometacin]			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760787	EXPEDITED (15-DAY)		DE	IT-MYLANLABS-2020M1044962		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761128	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI-1231758		50 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Hydroxychloroquine Sulphate Bp 200mg Tablet			S	Oral	200 Mg; 15.4. In The Evening And 16.4. In The Morning 400 Mg, Then		Teva

				200 Mg/12 H	
	Daleron 500 Mg	S	Oral	500 Mg; As Necessary, Dotal Dose Of 2 Tbl On 14. And 15.4.	Not Reported
	Fragmin 5000 Ie	S	Subcutaneous	5000iu; 5000/24 Ur	Not Reported
	Pantoprazol Teva 20 Mg	C	Oral	20 Milligram Daily;	Not Reported
	Folkodin Alkaloid-Int	C	Oral	10 Mg; As Necessary 2caps/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761229	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591156		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761316	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231938			Female	CAN

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

Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Leflunomide	S	Unknown	10 Milligram Daily;	Barr
	Cosentyx	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride	S	Unknown		Not Reported
	Penicillin G	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Cetirizine	C		20 Milligram Daily;	Not Reported
	Enbrel	C			Not Reported
	Lasix	C			Not Reported
	Montelukast	C		10 Milligram Daily;	Not Reported
	Synthroid	C		75 Microgram Daily;	Not Reported
	Terbutaline Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761340	EXPEDITED (15-DAY)		HO, OT	PT-ADVANZ PHARMA-GSH201712-006713			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisolone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	25 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	2 G, Qd		Not Reported
	Cyclophosphamide			C	Unknown	Unk		Not Reported
	Azathioprine			C	Intracardiac	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761350	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232520		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Naproxen			S	Unknown	1000 Milligram Daily;		Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761415	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232499		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea;	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral	2.6 Milligram Daily;	Not Reported
	Triamcinolone		S	Other		Not Reported
	Sulfasalazine		S	Oral	250 Milligram Daily;	Not Reported
	Triamcinolone Hexacetonide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761416	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232985		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Anakinra			S	Unknown	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761468	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232206		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761502	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1045105		62 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatitis; Long Qt Syndrome	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761537	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231771			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Advair			C				Not Reported
	Allopurinol			C				Not Reported
	Atrovent Hfa			C				Not Reported
	Codeine			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Dilaudid			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Ibuprofen			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Sulfasalazine			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761541	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2020-CA-1231733		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone	Leflunomide			S	Unknown	10 Milligram Daily;		Barr

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761575	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045111		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Sedacion		Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan
	Dexametasona /00016001/			C	Intravenous (not otherwise specified)	4 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761605	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1233076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Naproxen Sodium			S	Unknown			Teva
	Indomethacin			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761786	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2020M1046273		39 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Mylan

	Triamcinolone Acetonide	S		Intralesional Injection	Mylan
	Isoniazid	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761846	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1045048		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptococcosis; Hepatitis Toxic; Off Label Use	Methotrexate			S	Unknown	Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	750 Milligram/Sq. Meter, Q2w		Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Cellcept /01275102/			S	Unknown	0.5 Gram, Qd		Mylan
	Cellcept /01275102/			S	Unknown	2 Gram, Qd		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762248	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233084		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Metoprolol			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Apo-Metoprolol			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Naproxen Sodium	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762464	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232561		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Naproxen			S	Unknown	1500 Milligram Daily;		Teva
	Naproxen			S		1500 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Plaquenil			C				Not Reported
	Synthroid			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762507	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594982		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	7.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762702	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020185605		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Mg, Every 8 Hours		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Paracetamol			S	Oral	1 G, Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762783	EXPEDITED (15-DAY)		HO, LT, OT	JP-OSMOTICA_PHARMACEUTICAL_US_LLC-POI0573202000331		41 YR	Female	JPN

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

Exposure During Pregnancy; Haemorrhage; Hormone Level Abnormal; Hypogonadism; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Uterine Obstruction	Divigel	S	Transdermal	1.44 To 2.88 Mg Every 2 Days Each Between Fet 1 And Fet 4	Osmotica
	Divigel	S	Transdermal	1.44 Mg Every 2 Days During Fet 5	Osmotica
	Divigel	S	Oral	1.5 To 3.0 Mg Per Day During Fet 5	Osmotica
	Tacrolimus Monohydrate	S			Not Reported
	Progesterone	S	Vaginal		Not Reported
	Dydrogesterone	S	Oral		Not Reported
	Prednisolone	S			Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17763134	EXPEDITED (15-DAY)		DE	CN-FRESENIUS KABI-FK202004535		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated; Respiratory Failure	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17763193	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232108		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actonel	S	Unknown		Not Reported
	Actonel	S	Unknown		Not Reported
	Actonel	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17763198	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232213		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone	Leflunomide			S	Unknown			Barr

Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate	S	Unknown			Barr
	Naproxen Sodium	S	Unknown			Teva
	Prednisone	S	Unknown			Actavis
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17765180	DIRECT	Y	DE			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sars-Cov-2 Test Positive	Hydroxychloroquine Sulfate Tablet			S	Oral			Actavis
	Lorazepam			C				Not Reported
	Morphine			C				Not Reported
	Sodium Chloride 0.9%			C				Not Reported
	Cefepime			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Zosyn			C				Not Reported
	Azithromycin			C				Not Reported
	Venofer			C				Not Reported
	Kphos			C				Not Reported
	D5w			C				Not Reported
	1/2ns			C				Not Reported
	Acetaminophen			C				Not Reported
	Acetylcysteine			C				Not Reported
	Ascorbic Acid			C				Not Reported

	Bumetanide	C	Not Reported
	Benadryl	C	Not Reported
	Enoxaparin	C	Not Reported
	Insulin Regular	C	Not Reported
	Magnesium Hydroxide	C	Not Reported
	Propofol	C	Not Reported
	Reglan	C	Not Reported
	Zofran	C	Not Reported
	Versed	C	Not Reported
	Protonix	C	Not Reported
	Kayexalate	C	Not Reported
	Zinc	C	Not Reported
	Succinylcholine	C	Not Reported
	Etomidate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17765469	DIRECT	N	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Humira Cf 40mg			S	Subcutaneous	Other Frequency:Once Every;		Abbvie
	Sulfasalazin			C				Not Reported
	Acyclovir			C				Not Reported
	Armour Thyro			C				Not Reported
	Gabapentin			C				Not Reported
	Hydroxychlor			S				Not Reported
	Pilocarpine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	11610346	EXPEDITED (15-DAY)		HO	CA-ROCHE-1643242		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Decreased Immune Responsiveness; Immune System Disorder; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	13303877	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-1902159		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	15344061	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177451		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17240286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514006		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Surgical Failure; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17287257	EXPEDITED (15-DAY)		HO	CA-ROCHE-2520375		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Apo-Prednisone	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Amitriptyline	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17420209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543007		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	3 Years		Not Reported
	Humira			S	Subcutaneous	3 Months		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Unknown	9.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17655678	EXPEDITED (15-DAY)		DE, LT	FR-TEVA-2020-FR-1221608		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Lasilix 20 Mg/2 Ml, Solution Injectable En Ampoule			S	Intravenous (not otherwise specified)	2 Dosage Forms		Not Reported
	Plaquenil			S	Oral			Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)			Not Reported
	Perfalgan 10 Mg/Ml, Solution Pour Perfusion			C	Intravenous (not otherwise specified)			Not Reported
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)			Not Reported

Midazolam	C	Intravenous (not otherwise specified)			Not Reported
Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion	C	Intravenous (not otherwise specified)	4 Dosage Forms		Not Reported
Transipeg	C	Oral			Not Reported
Potassium (Chlorure De)	C	Intravenous (not otherwise specified)			Not Reported
Nimbex	C	Intravenous (not otherwise specified)			Not Reported
Effexor L.P. 37,5 Mg, Gelule A Liberation Prolongee	C	Oral			Not Reported
Ultibro Breezhaler	C	Respiratory (inhalation)			Not Reported
Seresta 10 Mg, Comprime	C	Oral			Not Reported
Rocephine	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17760306	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231595		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Dosage Forms		Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17762677	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis;	Rituxan			S	Intravenous drip			Not Reported
	Humira			S	Subcutaneous			Not Reported

White Blood Cell Count Decreased	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 7.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Actemra	C	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported
	Arava	C			Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17762926	EXPEDITED (15-DAY)		HO, LT, OT	JP-STRIDES ARCOLAB LIMITED-2020SP005498		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Off Label Use; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Tacrolimus			S	Unknown	4 Milligram		Strides
	Prednisolone			S	Unknown	7.5 Milligram		Not Reported
	Prednisolone			S	Unknown	Dose Increased		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram		Not Reported
	Estradiol			S	Transdermal	Unk		Not Reported
	Progesterone			S	Vaginal	300 Milligram (Vaginal Tablet)		Not Reported
	Dydrogesterone			S	Oral	15 Milligram Per Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Oxytocin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594042		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Off Label Use; Pyrexia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592057		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Migraine; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
					Remicade		S	Intracavernous		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
09-May-2020	17763308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594865		53 YR	Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Rituxan			S	Intravenous drip				Not Reported	
	Apo-Leflunomide			S	Unknown				Not Reported	
	Cimzia			S	Subcutaneous				Not Reported	
	Enbrel			S	Subcutaneous	7.0 Months			Not Reported	
	Humira			S	Subcutaneous				Not Reported	
	Hydroxychloroquine			S	Unknown				Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported	
	Leflunomide			S	Unknown				Not Reported	
	Methotrexate			S	Unknown				Not Reported	
	Methotrexate			S	Unknown				Not Reported	
	Orencia			S	Unknown				Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)				Not Reported	
	Simponi			S	Subcutaneous				Not Reported	
	Sulfasalazine			S	Subcutaneous				Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763309	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594899		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763311	EXPEDITED (15-DAY)		DS	CA-ROCHE-2595012		48 YR	Female	CAN

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

	Esomeprazole	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763349	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232236		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763356	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232701		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763364	EXPEDITED (15-DAY)		OT	FR-ABBVIE-20K-056-3397056-00		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right	Kaletra 200/50			S	Oral	Comprimé Pelliculé		Not Reported
	Plaquenil			S	Oral	200 Mg, Comprimé Enrobé		Not Reported
	Amlodipine			C				Not Reported
	Alprazolam			C				Not Reported

Lovenox	C		Not Reported
Paracetamol	C		Not Reported
Candesartan Cilexetil	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763369	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1232936		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Metilprednisolona (888a)			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	560 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763370	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232934		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina			S	Subcutaneous	40 Mg		Not Reported
	Enoxaparina			S	Subcutaneous	60 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594953			Female	CAN

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

Drug Ineffective; Drug Intolerance; Nausea	Rituxan		S	Intravenous drip	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Arava		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763378	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594210		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763390	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763394	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232235		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Colchicina / Dicloverina			S	Oral	1 Dosage Forms		Not Reported
	Colchicina / Dicloverina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763429	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594157		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Celebrex	S			Not Reported
Enbrel	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763447	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595032		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763468	EXPEDITED (15-DAY)		OT	FR-ABBVIE-20K-056-3397060-00		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Electrocardiogram U-Wave Prominent	Kaletra 200/50			S	Oral	Comprimé Pelliculé		Not Reported
	Kaletra			S	Oral	80 Mg/20 Mg, Solution Buvable		Not Reported
	Cordarone			S	Oral	200 Mg, Comprimé Sécable		Not Reported
	Plaquenil			S	Oral			Not Reported
	Xarelto			C				Not Reported
	Levothyrox			C				Not Reported
	Xatral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763470	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1231930		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	2 Comp Cada 12 Horas El Primer Día Y Posteriormente 2 Comp Cada 24 H,		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763487	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232707		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide	Hidroxicloroquina (2143a)			S	Oral	Loading Dose: 400 / 12h And Then 200mg / 12h Unit Dose :200 Milligram		Teva
	Metoclopramida (1958a)			C	Intravenous (not otherwise specified)	10 Milligram		Not Reported

	Metamizol (111a)	C	Intravenous (not otherwise specified)	2 Gram	Not Reported
	Paracetamol (12a)	C	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Ipratropio (1067a)	C	Oral	20 Microgram	Not Reported
	Ceftriaxona (501a)	C		2 Gram	Not Reported
	Beclometasona (463a)	C	Respiratory (inhalation)		Not Reported
	Furosemida (1615a)	C	Intravenous (not otherwise specified)	20 Milligram	Not Reported
	Azitromicina (7019a)	C	Oral	500 Mg On The First Day Unit Dose :250 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763509	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232933		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported
	Propofol			S	Unknown			Not Reported
	Propofol			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos			S	Oral	A Compressed Breakfast And Dinner 200 Milligram		Not Reported
	Midazolam (2256a)			S	Unknown			Not Reported
	Midazolam (2256a)			S				Not Reported
	Kaletra			S	Oral			Not Reported
	Ceftriaxona (501a)			S	Unknown	Not Specified		Not Reported
	Manidon Hta 240 Mg Comprimidos De Liberacion Prolongada, 30 Comprimido			C				Not Reported
	Rilast Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Polvo Pa			C				Not Reported
	Omnic Ocas 0,4 Mg Comprimidos De Liberacion			C				Not Reported

	Prolongada Recubiertos Con					
	Simvastatina 20 Mg 28 Comprimidos	C				Not Reported
	Kalpress 160 Mg Comprimidos Recubiertos Con Pelicula, 28 Comprimidos (	C				Not Reported
	Cortic - Corticoide	C	Unknown	Low Dose Corticoids		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763514	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1232632		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged	Propranolol			S	Oral			Actavis
	Laroxyl 40 Mg/Ml, Solution Buvable			S	Oral	15 Gtt		Not Reported
	Zithromax 250 Mg, Comprime Pellicule			S	Oral	500 Milligram		Not Reported
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	400 Milligram		Not Reported
	Paracetamol			C	Oral	If Necessary		Not Reported
	Pantoprazole			C	Oral	20 Milligram		Not Reported
	Oxygene			C	Respiratory (inhalation)	1 Liters		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763517	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232553		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763537	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232935		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Amoxicilina / Acido Clavulanico			S	Intravenous (not otherwise specified)	1 Gr /8h		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	80 Mg Day		Not Reported
	Ceftazidima (189a)			S	Intravenous (not otherwise specified)	2gr/8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763552	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232937		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	120 Milligram Daily; Unit Dose: 60 Mg		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days		Not Reported
	Dexametasona (722a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763555	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232242		79 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763557	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232550		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;		Teva
	Roactemra 20 Mg/Ml, Concentrado Para Solucion Para Perfusion			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763558	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232237		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763644	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232241		84 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hidroxicloroquina (2143a)			S	Oral	400 Mg Loading Dose		Teva

	Azitromicina (7019a)			C	Oral	Followed By 200 Mg / Day, 200 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	12958296	EXPEDITED (15-DAY)		OT	CA-ROCHE-1627311		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Doses		Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 12 Months		Not Reported
	Orencia			S	Unknown	Therapy Duration: 7 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months		Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17721515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763679	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050282			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Qd		Zydus Pharm
	Plaquenil Sulfate			S	Oral	600 Milligram, Qd		Not Reported
	Effexor			S	Oral	150 Milligram, Qd		Not Reported

Acebutolol	C	Oral	400 Milligram		Not Reported
Oxazepam	C	Oral	100 Milligram		Not Reported
Enoxaparine Sodique	C	Subcutaneous	4000 International Unit		Not Reported
Macrogol 4000	C	Oral	2 Dosage Form		Not Reported
Amlodipine	C	Oral	10 Milligram		Not Reported
Zopiclone	C	Oral	7.5 Milligram		Not Reported
Nicardipine	C	Oral	60 Milligram		Not Reported
Hydrochlorothiazide	C	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763813	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595003		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

	Xeljanz	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prevacid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763889	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Naproxen			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Actavis
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pms-Azithromycin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763895	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232981		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell	Naproxen Sodium			S	Unknown			Teva
	Prednisone Acetate			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid	C	Subcutaneous		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763913	EXPEDITED (15-DAY)		DS	CA-ROCHE-2594699		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	12470327	EXPEDITED (15-DAY)		OT	CA-ROCHE-1776829		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	C	Unknown	Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	13111555	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878349		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Darifenacin			C				Not Reported
	Arava			C				Not Reported
	Ativan			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported
	Cortisone			C	Oral			Not Reported
	Dilaudid			C				Not Reported
	Darifenacin			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex [Orphenadrine Citrate]			C				Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium			C				Not Reported

Plantago Ovata	C			Not Reported
Synthroid	C			Not Reported
Vagifem	C	Vaginal		Not Reported
Diphenhydramine	C			Not Reported
Pantoprazole Sodium	C			Not Reported
Desoximetasone	C	Oral		Not Reported
Furosemide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	13116772	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878330		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	14222162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2026226			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	14682212	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1017484			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Neonatal Respiratory Distress Syndrome; Premature Baby	Prednisone			S	Transplacental	25 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	7.5 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	15263425	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Intramuscular	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	15458116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192139		60 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Off Label Use; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	Extended Release Tablet	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16387989	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain;	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported

Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Plaquenil		S	Oral	200 Milligram, Once A Day	Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Oral	500 Milligram, Once A Day	Not Reported
	Synthroid		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	Unk, Two Times A Day	Not Reported
	Depo-Medrol		C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16522648	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Enbrel			S	Unknown	1000 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16524371	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira			S	Subcutaneous				Not Reported
	Acetaminophen			C	Unknown				Not Reported
	Pregabalin			C	Oral	50 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16530361	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177463			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Citalopram Hydrobromide			C		40 Mg		Not Reported
	Prednisone			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17149990	EXPEDITED (15-DAY)		OT	FR-ACCORD-165350		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Off Label Use; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported
	Omeprazole			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17195982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498563			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17246962	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514284		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Zoledronic Acid			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17433987	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551545		43 YR	Female	CAN

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

Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan		S	Intravenous drip	Not Reported
	Arava		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17477145	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559556		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17683228	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004002752			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Shock	Hydroxychloroquine			S	Oral	600 Mg, Qd (Film-Coated		Concordia

				Tablet)	
	Hydroxychloroquine	S	Oral	400 Mg, Qd (Film-Coated Tablet)	Concordia
	Cordarone	S	Intravenous (not otherwise specified)	600 Mg, Qd	Not Reported
	Cordarone	S	Intravenous (not otherwise specified)	900 Mg, Qd	Not Reported
	Noradrenaline	C		Unk	Not Reported
	Anaklnra	C		Unk	Not Reported
	Aspirina	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17702366	EXPEDITED (15-DAY)		LT	FR-JNJFOC-20200420365		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Risperidone			S	Oral			Janssen
	Plaquenil			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported
	Acebutolol			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Enoxaparine Sodique			C	Subcutaneous			Not Reported
	Macrogol 4000			C	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Clomipramine			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Nicardipine			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17711495	EXPEDITED (15-DAY)		LT, OT	FR-ASTRAZENECA-2020SE54654		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Infection; Inflammation; Pyrexia; Respiratory Disorder	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Other			Not Reported
	Hydroxychloroquine Sulfate			S	Other			Not Reported
	Loxen (Loxoprofen Sodium)			S	Intravenous (not otherwise specified)			Not Reported
	Movicol			S	Other	2 Df Bag		Not Reported
	Midazolam			S	Intravenous (not otherwise specified)	5mg/Ml Daily		Not Reported
	Paracetamol			C	Other			Not Reported
	Paracetamol			C	Other			Not Reported
	Doliprane			C	Unknown			Not Reported
	Doliprane			C	Unknown			Not Reported
	Lasilix			C	Other			Not Reported
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Diffu K			C	Other			Not Reported
	Diffu K			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17711760	EXPEDITED (15-DAY)		OT	DE-SA-2020SA095744		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Granuloma; Infective Tenosynovitis; Joint Swelling; Leukocytosis; Mycobacterium Marinum	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi

Infection; Pain In Extremity; Papule; Scab; Skin Mass; Thrombocytosis	Sulfasalazine		S	Oral	2 Df, Bid (500 Mg)	Not Reported
	Prednisolone		S	Oral	4 Mg, Qd	Not Reported
	Prednisolone		S	Oral	15 Mg, Qd	Not Reported
	Prednisolone		S	Oral	30 Mg, Qd	Not Reported
	Prednisolone		S	Oral	7.5 Mg, Qd	Not Reported
	Prednisolone		S	Oral	20 Mg, Qd (Two Weeks Before Presentation)	Not Reported
	Prednisolone		S	Oral	5 Mg, Qd	Not Reported
	Prednisolone		S	Oral	40 Mg, Qd	Not Reported
	Prednisolone		S	Oral	20 Mg, Qd	Not Reported
	Prednisolone		S	Oral	10 Mg, Qd	Not Reported
	Prednisone		S		Increased To	Not Reported
	Prednisone		S		Unk	Not Reported
	Amlodipine		C			Not Reported
	Metoprolol		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17718785	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200431648		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling;	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Therapeutic Response
Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17759142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594369		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C				Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17759175	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698474		46 YR	Female	CAN

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

Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Actemra	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S			Not Reported
	Arava	S	Unknown	Therapy Duration 976.0	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown	Therapy Duration: 9 Years	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 10 Years	Not Reported
	Sulfasalazine	S	Oral	Therapy Duration 4 Years	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 9 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764083	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2020-022169		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Olanzapine Orodispersible Tablets			S	Oral	1 Dosage Form, Once A Day,		Aurobindo
	Plaquenil			S	Oral	Day 1: 400mg 2x/D; Day 2-4:		Not Reported

Trazodone Hydrochloride	S	Oral	1 Dosage Form, Once A Day,1/4		Not Reported
Clexane	C	Endocervical	Unk		Not Reported
Perindopril	C	Unknown	1 Dosage Form, Once A Day		Not Reported
Movicol	C	Unknown	1 Dosage Form, Once A Day		Not Reported
Levothyroxine	C	Unknown	1 Dosage Form, Once A Day		Not Reported
Metformin	C	Unknown	2 Dosage Form, Once A Day		Not Reported
Prolopa	C	Unknown	0.5 Dosage Form, Once A Day		Not Reported
Contramal	C	Unknown	1 Dosage Form, As Necessary		Not Reported
Kalium	C	Oral	Unk		Not Reported
Algostase Mono	C	Unknown	3 Dosage Form, Once A Day		Not Reported
Pradaxa	C	Unknown	Unk		Not Reported
Uni Diamicron	C	Unknown	60 Milligram, Two Times A Day		Not Reported
Magnetop	C	Oral	450 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764121	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246389		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Daily		Sun
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported
	Rocephine			S	Oral	2 Gram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764172	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202004004910			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Disease Recurrence; Hypertension; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764183	EXPEDITED (15-DAY)		HO, OT	MX-ADVANZ PHARMA-202004004989			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Azithromycine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764488	EXPEDITED (15-DAY)		HO, OT	FR-SA-2020SA119037		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Off Label Use; Purpura; Thrombocytopenia	Plaquenil			S	Oral	Unk		Sanofi
	Plaquenil			S				Sanofi
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Sanofi
	Azithromycin			S	Oral	Unk		Not Reported
	Esomeprazole Magnesium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Sanofi
	Noradrenaline [Norepinephrine]			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Nimbex [Cisatracurium Besilate]	C				Not Reported
	Loxen [Nicardipine Hydrochloride]	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sufentanil	C				Not Reported
	Hypnovel [Midazolam Hydrochloride]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593162			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764632	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764919	EXPEDITED (15-DAY)		OT	ES-SAKK-2020SA118587AA		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Dia		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra			S				Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg Dia		Sanofi
	Ceftriaxone			S	Intravenous (not otherwise specified)	2gr Dia		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764921	EXPEDITED (15-DAY)		OT	ES-SA-2020SA117856		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg		Sanofi
	Roactemra			S	Intravenous (not	600 Mg		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765001	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1046051		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Salbutamol			S	Respiratory (inhalation)	0.1 Milligram, Q6h		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Metoclopramida /00041901/			S	Intravenous (not otherwise specified)	10 Milligram, Q8h		Mylan
	Propofol			S	Intravenous (not otherwise specified)	Unk		Mylan
	Dolquine			S	Oral	400 Milligram, Bid		Mylan
	Ipratropio Bromuro			C	Respiratory (inhalation)	20 Microgram, Q6h		Mylan
	Enoxaparina Sodica			C	Subcutaneous	Unk		Mylan
	Cefotaxima /00497602/			C	Intravenous drip	4 Milligram, Bid		Mylan
	Midazolam			C	Intravenous drip	100 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765075	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-181155		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Quetiapine			S	Oral			Not Reported
	Levofloxacin/Levofloxacin Mesylate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Kaletra			S	Oral	200/50 Mg Film-Coated Tablets, 120 Tablets		Not Reported

	Losartan	C	Oral	Not Reported
	Clindamycin	C	Intravenous (not otherwise specified)	Not Reported
	Lorazepam	C	Oral	Not Reported
	Furosemide	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765732	EXPEDITED (15-DAY)		OT	SI-PFIZER INC-2020185753		50 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Fragmin			S	Subcutaneous	5000 Iu / 24 Hours		Pfizer
	Hydroxychloroquine Sulphate			S	Oral	On 15apr In The Evening And On 16apr In The Morning With Dose Of 400 Mg, Then 200 Mg/12 H		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Mg In The Evening		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Mg In The Morning		Not Reported
	Daleron			S	Oral	500 Mg; As Necessary, Total Dose Of 2 Tbl On 14apr And 15apr		Not Reported
	Pantoprazol Teva			C	Oral	20 Mg; 20 Mg/Day		Not Reported
	Folkodin Alkaloid			C	Oral	10 Mg; As Necessary 2caps/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765761	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765939	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594074			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tiaprofenic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592191		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Baclofen			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Sulfadiazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Arthritis; Rheumatoid Factor Positive; Synovitis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766223	EXPEDITED (15-DAY)		DS	CA-ROCHE-2596648		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766384	EXPEDITED (15-DAY)		OT	FR-ACCORD-181003		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin Sandoz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766429	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Hypoglycaemia	Hydroxychloroquine			S	Oral			Not Reported
	Glimeperide			C				Not Reported
	Cyclosporine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766486	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020185579		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer
	Azithromycin			S				Pfizer
	Metamizole			S	Intravenous (not otherwise specified)	2 G, 4x/Day (2 G Every 6 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (400 Mg/Day)		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, 3x/Day (1g Every 8 Hours)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766918	EXPEDITED (15-DAY)		HO	CA-SA-2020SA118445		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Plaquenil			S		Unk		Sanofi
	Arava			S				Sanofi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cortisone			S		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766966	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767571	EXPEDITED (15-DAY)		HO	IN-MYLANLABS-2020M1046274		29 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	100 Milligram Bid, Had Been Receiving For 2 Months		Not Reported
	Prednisolone			C	Unknown	30 Milligram, Qd		Mylan
	Prednisolone			C	Unknown	60 Milligram, Qd		Mylan
	Mycophenolate Mofetil			C	Unknown	1.5 Gram, 0.5 Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767604	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020185539		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Nausea; Off Label Use;	Zithromax			S	Oral	750 Mg, 1x/Day		Pfizer

Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767962	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-013311		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days		Bausch And Lomb
	Dexametasona			S				Bausch And Lomb
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S				Not Reported
	Enoxaparina			S	Subcutaneous			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Total		Not Reported
	Tocilizumab			S				Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17768202	EXPEDITED (15-DAY)		OT	US-EMERGENT BIOSOLUTIONS-20000341SP			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Narcan			S	Unknown	4 Milligram		Emergent Biosolutions
	Prednisone			S	Unknown			Not Reported
	Wellbutrin			S	Unknown	300 Milligram, Qd		Not Reported
	Wellbutrin			S	Unknown	150 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cyclobenzaprine Hcl			S	Unknown	Unk		Not Reported

	Hydrochlorothiazide			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17768204	EXPEDITED (15-DAY)		OT	US-EMERGENT BIOSOLUTIONS CANADA INC.-20000340SP		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Narcan			S	Unknown	4 Milligram		Emergent Biosolutions
	Plaquenil			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	150 Milligram, Qd		Not Reported
	Wellbutrin			S	Unknown	300 Milligram, Qd		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily; 60/Btl		Not Reported
	Cyclobenzaprine Hcl			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	12248361	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1737509		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Oropharyngeal Pain; Pain; Productive Cough; Spinal Operation; Sputum Discoloured; Thrombosis	Sulfasalazine		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Warfarin		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Apo-Prednisone		S	Unknown	Not Reported
	Apo-Warfarin		S	Unknown	Not Reported
	Amitriptyline		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	13224700	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890670			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	10/--/1997 To 02/--/1999, Duration- 2 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown	Duration- 11 Years		Not Reported
	Actemra			C	Unknown			Not Reported

FDA Adverse Event Reporting System
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Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	13995479	EXPEDITED (15-DAY)		OT	CA-ROCHE-1995131		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Baclofen			C				Not Reported
	Levaquin			C				Not Reported
	Baclofen			C				Not Reported
	Furosemide			C				Not Reported
	Gravol Ginger			C				Not Reported
	Potassium Chloride			C				Not Reported
	Valsartan			C				Not Reported
	Zingiber Officinale			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	14166039	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210592			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Oral	175 Mg,Qw		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg,Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	14739695	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104045		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	14746352	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Tylenol Arthritis Pain			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15343031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178204		56 YR	Female	CAN

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

Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituximab	S	Intravenous drip	Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Venlafaxine Hydrochloride	S	Unknown		Not Reported
	Venlafaxine Hydrochloride	S	Oral		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrodiuril	C	Unknown		Not Reported
	M-Eslon	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Morphine Sulfate	C	Unknown		Not Reported
	Venlafaxine Hydrochloride	C	Oral		Not Reported
	Statex [Morphine Sulfate]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15415874	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15562825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015053449		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Enbrel			S		Unk		Unknown
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	22.5 Mg, Qwk		Pfizer
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S		10 Mg, Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15875870	EXPEDITED (15-DAY)		OT	PHHY2019DE016444		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Restlessness	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Methotrexate			S	Unknown	17.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Benepali			S	Unknown	50 Mg, Qw		Not Reported
	Benepali			S	Unknown	50 Mg		Not Reported
	Hcq			S	Unknown	200 Mg, Unk		Not Reported
	Hcq			S	Unknown	300 Mg, Qd		Not Reported
	Tocilizumab			S	Unknown	162 Mg		Not Reported
	Chloroquine			C	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg		Not Reported
	Orencia			C	Unknown	125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15949612	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000034			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Nifedipine			S	Unknown	Unk		Validus
	Clopidogrel Bisulfate			S	Unknown	Unk		Not Reported
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported

	Trandolapril	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Unk	Not Reported
	Loperamide	S	Unknown	Unk	Not Reported
	Ambien	S	Unknown	Unk	Not Reported
	Gabapentin	S	Unknown	Unk	Not Reported
	Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
	Potassium	S	Unknown	Unk	Not Reported
	Glyceryl Trinitrate	S	Unknown	Unk	Not Reported
	Metoclopramide Hydrochloride	S	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	S	Unknown	Unk	Not Reported
	Isosorbide Mononitrate	S	Unknown	Unk	Not Reported
	Victoza	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qod	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Humira	S			Not Reported
	Flomax /00889901/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16043043	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S		20 Mg, Unk		Sanofi
	Hydroxychloroquine			S		400 Mg, Unk		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Actemra			S		8 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Orencia			S		750 Mg, Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk Unk, Unk	Not Reported
	Meloxicam	C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046577	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046593	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046595	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057730		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported
	Salazopyrin			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046597	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Mg		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	(4-6 Months Duration)		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16047223	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058618		33 YR	Female	CAN

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

Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Arava	S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil	S	Unknown	200 Mg, Qow		Sanofi
	Methotrexate	S	Intravenous (not otherwise specified)	20 Mg, Qw		Not Reported
	Actemra	S	Unknown	5 Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qw		Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Qw		Not Reported
	Methotrexate Sodium	S		20 Mg, Qw		Not Reported
	Remicade	S	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16048334	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16051263	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of	Arava			S	Oral	20 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Sulfasalazine			S	Unknown	1000 G, Unk		Not Reported

Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone		S	Oral	5 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	20 Mg, Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	50 Mg, Unk	Not Reported
	Humira		S	Unknown	20 Mg, Unk	Not Reported
	Orencia		S	Unknown		Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16075449	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012871		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Oral	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	680 Milligram, Every Month		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Everey 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram,11 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	780 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Every Month	Not Reported
Alendronate Sodium	C	Unknown	70 Milligram, Every Week	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16462890	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1910		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Cyclosporin			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Mercaptopurine	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Tenoxicam	C	Unknown	Not Reported
	Ustekinumab	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16537906	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA177580		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Hydroxychloroquine			S	Oral	400 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	0.8 Ml, Qw		Not Reported
	Leflunomide			S	Unknown	Unk, Unk		Sanofi
	Prednisone			S	Unknown	Unk, Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16753500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2384248		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Zostavax		S	Subcutaneous	Therapy Duration-1.0 Day(S)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16878285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107873		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Atorvastatin Calcium			C				Not Reported
	Bisoprolol			C				Not Reported
	Digoxin			C				Not Reported
	Folic Acid			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Naproxen			C				Not Reported
	Nifedipine			C				Not Reported
	Synthroid			C				Not Reported

	Toloxin [Digoxin]	C	Not Reported
	Valsartan	C	Not Reported
	Xarelto	C	Not Reported
	Zinc Citrate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16913173	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2428710		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Apremilast	S	Unknown	Not Reported
Apo-Ibuprofen	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Infliximab	S	Oral	Not Reported
Ibuprofen	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Motrin [Ibuprofen]	S	Oral	Not Reported
Otezla	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Alendronate	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C		Not Reported

	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Colchicine	C	Oral	Not Reported
	Dexilant	C	Unknown	Not Reported
	Febuxostat	C		Not Reported
	Folic Acid	C		Not Reported
	Gravol	C		Not Reported
	Mogadon	C	Oral	Not Reported
	Nitrazepam	C	Oral	Not Reported
	Oxycodone	C		Not Reported
	Uloric	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17233158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511749			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17286449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17324328	EXPEDITED (15-DAY)		OT	MQ-ALKEM LABORATORIES LIMITED-MQ-ALKEM-2020-00067		53 YR	Female	MTQ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Hyperkeratosis	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17438985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552195			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17477176	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2557988			Female	CAN

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

Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17506284	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560155		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Minocycline	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Amoxicillin;Clavulanate Potassium	C		Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported
Adalimumab	C		Not Reported
Amoxicillin	C		Not Reported
Amoxicillin Trihydrate	C		Not Reported
Amoxicillin Trihydrate;Clavulanate Potassium	C		Not Reported
Bcg Vaccine	C	Unknown	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Hydroxychloroquine	C	Subcutaneous	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

	Risedronate	C	Oral	Not Reported
	Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17531084	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2563674		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17716028	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004070			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Off Label Use;	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Ceftriaxone			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Oxazepam			C		Unk		Not Reported

Renal Failure; Respiratory Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17719494	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1227982		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Cardiotoxicity	Hydroxychloroquine			S	Unknown			Teva
	Rituximab			C	Unknown			Not Reported
	Cyclophosphamide			C	Unknown			Not Reported
	Doxorubicin Hydrochloride			C	Unknown			Not Reported
	Vincristine			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17720141	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020167361		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Levofloxacin			S		Unk		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Df, 2x/Day		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17737424	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-021232		96 YR	Male	ITA

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

Arrhythmia; Extrasystoles; Off Label Use	Azithromycin Film-Coated Tablets		S	Unknown	500 Milligram, Once A Day	Aurobindo
	Plaquenil		S	Unknown	400 Milligram, Once A Day	Not Reported
	Lasix		C	Unknown	25 Milligram, Once A Day	Not Reported
	Novorapid		C	Unknown	Unk	Not Reported
	Normix		C	Unknown	Unk	Not Reported
	Dobetin		C	Unknown	Unk	Not Reported
	Lantus		C	Unknown	Unk	Not Reported
	Movicol		C	Unknown	Unk	Not Reported
	Deltacortene		C	Unknown	Unk	Not Reported
	Pantorc		C	Unknown	20 Milligram, Once A Day	Not Reported
	Cardirene		C	Unknown	75 Milligram, Once A Day	Not Reported
	Metoprololo		C	Unknown	50 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17763611	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1045811		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg/12h		Not Reported
	Hydroxychloroquine			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2gr/24h		Mylan
	Ceftriaxona /00672201/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768365	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug	Rituximab			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768422	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596002			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Varilrix			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Oral			Not Reported

	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768752	EXPEDITED (15-DAY)		HO	CA-ROCHE-2593341			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride;Paracetamol;Phenylephrine Hydrochloride			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral	Therapy Duration: 4.0 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tylenol	S	Unknown		Not Reported
	Synthroid	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768780	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595810		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768816	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-023990		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Cefditoren Pivoxil			S	Oral	400 Milligram, Two Times A Day		Not Reported
	Cefditoren Pivoxil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768910	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246775		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	800 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769128	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595786		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate Sodium	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769203	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596166			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769259	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3399543-00		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Kaletra 200/50			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported

	Azitromicina	S	Intravenous (not otherwise specified)	Not Reported
	Dolquine	S	Oral	Not Reported
	Enalapril + Hidroclorotiazida	C	Oral	Not Reported
	Omeprazol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769297	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050486			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Zydus Pharm
	Plaquenil Sulfate			S	Oral	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596608		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Loperamide			C				Not Reported

	Pantoprazole	C			Not Reported
	Xeljanz	C			Not Reported
	Align	C			Not Reported
	Actemra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769595	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596962			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769616	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004005067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Ineffective; Drug Intolerance; Joint Swelling; Psoriatic Arthropathy; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Fish Oil			S	Oral	Unk, Qd		Not Reported
	Inflectra			S	Unknown	5 Mg/Kg Q 0, 2, 6 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769657	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004987			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Death; General Physical Health Deterioration; Off Label Use; Tachypnoea	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia
	Alfuzosine [Alfuzosin]			C		Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Macrogol			C		Unk		Not Reported
	Nebivolol			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Calciparine			C		Unk		Not Reported
	Fresubin [Caffelne;Carbohydrates Nos;Fats Nos;Flbre, Dletary;Mlnerals			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769658	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004004919			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770015	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596364			Female	CAN

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

Drug Ineffective; Psoriatic Arthropathy; Synovitis	Rituximab	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770068	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004005236			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopia; Retinopathy; Systemic Lupus Erythematosus; Visual Acuity Reduced	Hydroxychloroquine			S		600 Mg, Qd		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770137	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595745			Male	CAN

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

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770159	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001362			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Cornea Verticillata; Corneal Toxicity; Eyelid Ptosis; Punctate Keratitis	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	1200 Milligram, Qd		Ipca
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770289	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235380		58 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770291	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234164			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770292	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1234235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dehydration; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770293	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235381		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug	Prednisone			S	Unknown			Actavis

Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Methotrexate		S	Subcutaneous	Barr
	Acetaminophen		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Dilaudid		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770303	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596964		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Infusion Related Reaction; Off Label Use; Pharyngeal Swelling; Poor Venous Access; Vasculitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Epinephrine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Fentanyl			C				Not Reported
	Losartan			C				Not Reported
	Mirtazapine			C				Not Reported
	Progesterone			C				Not Reported
	Rabeprazole			C				Not Reported
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770331	EXPEDITED (15-DAY)		HO, LT, OT	JP-ACCORD-181070		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Exposure During Pregnancy; Hormone Level Abnormal;	Tacrolimus			S				Accord
	Estradiol			S	Transdermal			Not Reported
	Progesterone			S	Vaginal			Not Reported

Hypogonadism; Infarction; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Dydrogesterone		S	Oral	Not Reported
	Prednisolone		S		Not Reported
	Hydroxychloroquine		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770353	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235370		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770367	DIRECT	Y	HO, OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachyarrhythmia	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin 500mg Daily			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770369	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Headache; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cimzia	C	Subcutaneous	Not Reported
	Enbrel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770516	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596382		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Rituximab			S	Unknown	Therapy Duration: 7.0 Years		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770677	DIRECT	Y	HO, OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Extrasystoles	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770905	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020185534		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770950	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057628		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Leukopenia; Nausea; Treatment Failure; Vomiting; Weight Decreased	Arava			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	300.0 Mg, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15.0 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771123	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1045657		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Sotalol			S	Oral	80 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771147	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595696		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown	3.0 Months		Not Reported
	Methotrexate			S	Unknown	366.0		Not Reported
	Arava			S	Unknown	366.0		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	366.0		Not Reported
	Lyrica			S	Unknown	366.0		Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Tylenol Extra Strength			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771350	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202004004924			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Bilirubin Conjugated Abnormal; Blood Creatinine Increased; Death; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771351	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004723			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Macular Degeneration; Toxicity To Various Agents	Hydroxychloroquine			S		Unk, Duration For Less Than 3 And Half Yeas		Concordia
	Prednisone			S		Unk,10 To 20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771443	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045786		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Ertapenem			S	Intravenous (not otherwise specified)	1 G Dia		Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771446	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045819		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 G Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590775		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported

	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771612	EXPEDITED (15-DAY)		HO, LT	ES-PFIZER INC-2020187944		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Off Label Use; Pancreatitis Acute; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	250 Mg, 1x/Day		Pfizer
	Kaletra			S	Oral	2 Df, 2x/Day (Every 12 Hours)		Not Reported
	Ceftriaxon			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported
	Dolquine			S	Oral	200 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771649	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2591841		60 YR	Female	CAN

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

Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Actemra		S	Unknown		Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe (Subcutaneous Solution)	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Subcutaneous Solution	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution (Intravenous)	Not Reported
	Simponi		S	Subcutaneous	Subcutaneous Solution	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771827	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2020185943		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Rash Pustular	Norvasc			S	Oral	10 Mg, 1x/Day		Pfizer
	Norvasc			S		Unk (Reduced Dose)		Pfizer
	Ritonavir			S	Oral	100 Mg, 1x/Day		Not Reported
	Clexane T			S	Subcutaneous	6000 Kiu, 1x/Day		Not Reported
	Darunavir			S	Oral	800 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Azithromycin Teva			S	Oral	500 Mg, 1x/Day		Not Reported

	Eutirox	C		Unk	Not Reported
	Folifill	C		Unk	Not Reported
	Ceftriaxone	C	Oral	1 Df, 1x/Day	Not Reported
	Lasix [Furosemide]	C		Unk	Not Reported
	Urbason Solub	C	Intravenous (not otherwise specified)	1 Df, 1x/Day	Not Reported
	Omeprazole	C		Unk	Not Reported
	Trelegy Ellipta	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17772487	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20200512027			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Darunavir			S	Unknown			Janssen
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17773499	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3399921-00		67 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Rash Pruritic	Kaletra 200/50			S	Oral			Not Reported
	Levofloxacino			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17773527	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-024316		72 YR	Male	ESP

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

Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Meropenem	S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day	Aurobindo
	Piperacillin+Tazobactam 4.5g	S	Intravenous (not otherwise specified)	1 Dosage Form, 3 Times A Day	Aurobindo
	Linezolid	S	Intravenous (not otherwise specified)	600 Milligram, Two Times A Day	Aurobindo
	Roactemra	S	Unknown	600 Milligram,1 Total	Not Reported
	Roactemra	S			Not Reported
	Metamizole	S	Intravenous (not otherwise specified)	2 Gram, 3 Times A Day	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	11176748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1589866		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)	Discontinued After 2 Cycles, Therapy Duration: 4 Months.		Not Reported
	Humira			S	Subcutaneous	For 4 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	Therapy Duration: 4 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported
	Tofacitinib			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	12678680	EXPEDITED (15-DAY)		OT	CA-ROCHE-1817079		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	12884262	EXPEDITED (15-DAY)		OT	CA-ROCHE-1734356		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug	Actemra			S	Unknown	Discontinued		Not Reported
	Enbrel			S	Unknown	Discontinued		Not Reported
	Orencia			S	Unknown	Discontinued		Not Reported

Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Arava		S	Unknown	Therapy Duration: 4 Months	Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Prednisone		C			Not Reported
	Folic Acid		C			Not Reported
	Naproxen		C			Not Reported
	Advil [Ibuprofen]		C			Not Reported
	Ketorolac		C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown		Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	12988986	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ROCHE-1860198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Ilaris	S	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	13203126	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889218		60 YR	Female	CAN

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

Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclical	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

Orencia	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	13842763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1973086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Arava	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Rituxan	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Mobicox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	15364714	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2181752		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo Hydromorphone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Acetaminophen	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Alendronate Sodium;Colecalciferol	C	Unknown	Not Reported
	Alendronate Sodium;Colecalciferol	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Hydrocortisone	C	Nasal	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Methylprednisolone	C		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Remicade	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	15843027	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20190118848		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Foot Deformity; Foot Operation; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			S	Unknown			Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Risedronic Acid	S	Unknown		Not Reported
Hydroxychloroquine	C	Oral		Not Reported
Hydroxychloroquine	C			Not Reported
Risedronate	C	Unknown		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16046574	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057903		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Exostosis; Osteoarthritis; Pain In Extremity; Pulmonary Thrombosis; Thrombosis	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Bid		Sanofi
	Pantoprazole			C	Unknown	40 Mg, Qd		Not Reported
	Pravastatin			C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16055947	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057819		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye;	Arava			S	Oral	20 Mg, Qd		Sanofi
	Gabapentin			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	100 Mg, Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi

Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure; Unevaluable Event; Unevaluable Event	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Sanofi
	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Q3w	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Qm	Not Reported
	Omega 3 [Fish Oil]	C	Oral	1200 Mg, Bid	Not Reported
	Omega 3 [Fish Oil]	C	Unknown	Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Actonel	C	Unknown	36 Mg, Qw	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	40 Mg, Bid	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
	Genteal [Hypromellose]	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Nexium [Esomeprazole	C	Unknown	Unk	Not Reported

Magnesium]				
Nicotinamide	C	Unknown	Unk Unk, Bid	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Qcy	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	400 Mg, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone [Trazodone Hydrochloride]	C	Oral	50 Mg, Qcy	Not Reported
Tylenol [Paracetamol]	C	Unknown	50 Mg, Qcy	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
Vitamin B12 [Vitamin B12 Nos]	C	Unknown	Unk	Not Reported
Vitamin D [Vitamin D Nos]	C	Unknown	400 Df, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Qd	Not Reported
Thiamine Hcl	C			Not Reported
Oxycodone And Acetaminophen	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16341891	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000245			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Nifedipine			S	Unknown	Unk		Validus
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported

Trandolapril	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Plavix	S	Unknown	Unk	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	S	Unknown	Unk	Not Reported
Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	S	Unknown	Unk	Not Reported
Trazodone Hydrochloride	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	S	Unknown	Unk	Not Reported
Ambien	S	Unknown	Unk	Not Reported
Gabapentin	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Flomax /00889901/	S	Unknown	Unk	Not Reported
Isosorbide Mononitrate	S	Unknown	Unk	Not Reported
Potassium Acetate	S	Unknown	Unk	Not Reported
Victoza	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Doxycycline Hyclate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16388022	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029850		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain;	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported

Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac	S	Oral	75 Milligram, As Necessary	Not Reported
	Diclofenac	S	Oral	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Every Week	Not Reported
	Plaquenil	S	Oral	200 Milligram, Once A Day	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 Gram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Once A Day	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Tecta	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	10 Milligram, Once A Day	Not Reported
	Voltaren	S	Oral	75 Milligram, Two Times A Day	Not Reported
	Voltaren	S	Oral	Unk	Not Reported
	Apo-Folic Acid	S	Unknown	Unk	Not Reported
	Apo-Diclofenac	S	Oral	75 Milligram, Two Times A Day	Not Reported
	Apo-Diclofenac	S	Oral	75 Milligram	Not Reported
	Apo-Lisinopril	S	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16740198	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0113518			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of		Not Reported

Peripheral; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment				The Interval: Hour		
	Ramipril		S			Not Reported
	Omeprazole		S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Not Reported
	Omeprazole		S		20 Mg, Bid	Not Reported
	Sildenafil		S	Unknown	60 Milligram, Daily Dose	Not Reported
	Volibris		S	Oral	30 Milligram, Qd	Not Reported
	Volibris		S	Oral	1 Dosage Form, Qd	Not Reported
	Roactemra		S	Subcutaneous	162 Mg, Qw	Not Reported
	Roactemra		S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Quensyl		S	Unknown	1 Df, Bid (1-0-1)	Not Reported
	Quensyl		S	Unknown	1 Df, Bid (1-0-1)	Not Reported
	Eliquis		S	Unknown	1 Df, Bid (1-0-1)	Not Reported
	Spasmolyt		S		1 Df, Qd (1-0-1)	Not Reported
	Spasmolyt		S	Unknown	30 Mg (0 -0 -1)	Not Reported
	Spasmolyt		S	Unknown	15 Mg, Qd	Not Reported
	Ambrisentan		S	Unknown		Not Reported
	Ambrisentan		S	Unknown	30 Milligram, Qd	Not Reported
	Ambrisentan		S	Unknown		Not Reported
	Ambrisentan		S			Not Reported
	Lyrica		S	Unknown	100 Milligram, Tid	Not Reported
	Lyrica		S	Unknown	100 Milligram, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17046117	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2465588		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial: Powder For Solution For Injection	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
	Remicade	S	Unknown		Not Reported

Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S		Not Reported
Cannabis Sativa	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Rituximab	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Anakinra	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17114110	EXPEDITED (15-DAY)		OT	CA-SA-2019SA336230			Female	CAN

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

Sulfasalazine	S	Unknown	2 Gm (1 Gm,1 In 12 H)	Not Reported
Cortisone Acetate	S	Unknown	25 Mg	Not Reported
Cimzia	S	Subcutaneous	Unk (Single-Use Prefilled Syringe)	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Mg, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17407151	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698470		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain;	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	5.0 Months		Not Reported
	Gold			S	Unknown	7.0 Months		Not Reported

Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	3.0 Years	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17416504	EXPEDITED (15-DAY)		HO	US-ACTELION-A-US2020-201797		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Blood Culture Positive; Brevibacterium Infection; Catheter Management; Catheter Site Infection; Device Related Infection; Diarrhoea; Dyspnoea Exertional; Ear Infection; Immunosuppression; Sepsis	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Veletri			S	Intravenous (not otherwise specified)	28 Ng/Kg, Per Min		Actelion
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Letairis			C				Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17558038	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318943		63 YR	Female	CAN

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

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Pain; Rheumatic Fever; Rheumatoid Arthritis; Spinal Stenosis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Unevaluable Event; Urinary Tract Infection	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Topicort /00028604/	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Gold	C		Not Reported
	Morphine	C	Unknown	Not Reported
	Tofacitinib	C	Oral	Not Reported
	Acetaminophen W/Dextropropoxyphene	C		Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17586718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015347561		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Lower Respiratory Tract Infection; Pain	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S	Unknown	Unk		Not Reported

	Plaquenil	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17655387	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3357377-00		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17730576	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437119		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Leukopenia; Mouth Ulceration; Patient Dissatisfaction With Treatment	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17743416	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437389		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17743992	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437152		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17744189	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436841		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product	Remicade			S	Intravenous (not otherwise specified)			Janssen

Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Alprazolam	C	Unknown	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Asa	C		Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Paroxetine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Simvastatin	C	Unknown	Not Reported
	Statex /00036302/	C	Unknown	Not Reported
	Telmisartan	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747079	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200437399		42 YR	Female	CAN

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

Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Remicade		S	Intravenous (not otherwise specified)	Janssen
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747993	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437162		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Amlodipine	C			Not Reported
Benadryl /00000402/	C			Not Reported
Arava	C			Not Reported
Naproxen	C	Unknown		Not Reported
Prednisone	C			Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Viread	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17751807	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17757930	EXPEDITED (15-DAY)		LT, OT	JP-BAUSCH-BL-2020-013339		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal	Prednisolone			S	Unknown			Not Reported

Newborn; Placenta Accreta	Prednisolone		S	Unknown	Increased Dose	Not Reported
	Estradiol		S	Transdermal	Until 10 Weeks Of Gestation	Not Reported
	Tacrolimus Hydrate		S	Unknown		Not Reported
	Progesterone		S	Vaginal	Until 10 Weeks Of Gestation	Not Reported
	Dydrogesterone		S	Oral		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Oxytocin		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773117	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-023950		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Aurobindo
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sufentanil			C	Unknown	Unk		Not Reported
	Nimbex			C	Unknown	Unk		Not Reported
	Hypnovel			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773297	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202004004918			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Norepinephrine			C		Unk		Not Reported
	Ceftazidime			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Trimethropim Sulfamethoxazole			C		Unk		Not Reported
	Lineozlid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595675		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Drug Ineffective; Gait Disturbance; Gait Inability; Hypoaesthesia; Joint Swelling; Musculoskeletal Pain; Neck Pain; Peripheral Swelling; Pharyngeal Oedema; Rash; Therapeutic Product Effect Decreased	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773503	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202003004282			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773686	EXPEDITED (15-DAY)		DE, HO	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245681		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated; Respiratory Failure	Hydroxychloroquine			S	Oral	Unk		Sun
	Methylprednisolone			S	Unknown	200 Milligram, Daily		Not Reported
	Prednisone			S	Unknown	40 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773712	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-024314		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Dia		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported
	Enoxaparin			S	Subcutaneous	80 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773717	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595963		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773731	EXPEDITED (15-DAY)		DE	ES-AUROBINDO-AUR-APL-2020-024369		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

	Tocilizumab		S	Intravenous (not otherwise specified)	600 Milligram, Total	Not Reported
	Tocilizumab		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773862	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595816			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596145		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous drip			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Acetaminophen	C		Not Reported
	Codeine	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773971	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246369		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Daily		Not Reported
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported
	Haloperidol			S	Oral	5 Gtt Drops, Daily		Not Reported
	Haloperidol			S	Oral	5 Gtt Drops		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596655			Female	CAN

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

Arthralgia; Contraindicated Product Administered; Deformity; Ill-Defined Disorder; Malaise; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Actemra	S	Subcutaneous			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Certolizumab Pegol	S	Subcutaneous			Not Reported
	Codeine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774166	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001325			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Nausea	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Ipca
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Ipca
	Fluoxetine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Levothyroxine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Cerazette			C	Unknown	1 Dosage Form, Qd		Not Reported
	Colecalciferol			C	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595905		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596306		59 YR	Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774409	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005235			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	400 Mg		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Adalimumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774424	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-013591		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Doxiciclina			S	Oral			Not Reported
	Doxiciclina			S				Not Reported
	Azitromicina			S	Oral			Not Reported
	Azitromicina			S				Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774466	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1233693		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774467	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233697		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported
	Lopinavir/Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774847	EXPEDITED (15-DAY)		DS	CA-ROCHE-2595829		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Gold	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Actemra	C	Unknown	Not Reported
Arava	C	Oral	Not Reported
Bifidobacterium Bifidum	C		Not Reported
Celebrex	C	Unknown	Not Reported
Loperamide	C		Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Unknown	Not Reported
Pantoprazole	C		Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C		Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17775254	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANZ PHARMA-GSH201706-003681			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate			S	Oral	Unk		Concordia

Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate	S	Unknown	Unk	Concordia
	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate	S	Unknown	Unk	Concordia
	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate	S	Unknown	Unk	Concordia
	(Authorized Generic),Plaquenil Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Concordia
	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Concordia
	(Authorized Generic),Plaquenil Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported

Humira	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Gold	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	C			Not Reported
Methotrexate	C			Not Reported
Hydroxychloroquine Phosphate	C		Unk	Not Reported
Rituximab	C			Not Reported
Anakinra	C			Not Reported
Lyrica	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17776951	EXPEDITED (15-DAY)		HO, LT	SI-ACCORD-181639		48 YR	Male	SVN

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

Immune Thrombocytopenia; Thrombocytopenia	Hydroxychloroquine	S	Oral	Strength: 200 Mg	Not Reported
	Kaletra	S	Oral	(80mg+20mg)/Ml Oral Solution, Dose 400mg/100 Mg	Not Reported
	Piperacillin Sodium/Tazobactam Sodium	C			Not Reported
	Esmeron	C			Not Reported
	Metoclopramide	C			Not Reported
	Analgin	C			Not Reported
	Pantoprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598053			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777448	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201902-000277			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Plavix			S	Unknown	Unk		Not Reported
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Trandolapril			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Loperamide			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Nexium			S	Unknown	Unk		Not Reported

	Crestor	S	Unknown	Unk	Not Reported
	Potassium Acetate	S	Unknown	Unk	Not Reported
	Glyceryl Trinitrate	S	Unknown	Unk	Not Reported
	Victoza	S	Unknown	Unk	Not Reported
	Humira 40 Mg/0.8 Ml	S	Subcutaneous	40 Mg, Qod	Not Reported
	Humira 40 Mg/0.8 Ml	S	Subcutaneous	40 Mg,Qow	Not Reported
	Humira 40 Mg/0.8 Ml	S			Not Reported
	Flomax	S	Unknown	Unk	Not Reported
	Reglan	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	Unk	Not Reported
	Imdur	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235410		30 YR	Female	CAN

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

Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Prednisone		S	Unknown	Actavis
	Cymbalta		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778115	EXPEDITED (15-DAY)		OT	FR-APPCO PHARMA LLC-2083741		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778165	EXPEDITED (15-DAY)		OT	FR-APPCO PHARMA LLC-2083742		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778290	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC-2020185611		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Off Label Use; Pneumonia Escherichia; Product Use In Unapproved Indication; Ventricular Tachycardia	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593495		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Not Reported
Topicort [Desoximetasone]	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported

Salazopyrin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778359	EXPEDITED (15-DAY)		HO, OT	MX-APPCO PHARMA LLC-2083743		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma
	Prednisone			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778367	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2020SE60059		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Inexium			S	Intravenous (not otherwise specified)			Astrazeneca
	Cefotaxime Base			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycine Anhydrous			S	Oral			Not Reported
	Noradrenaline			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Loxen [Nicardipine Hydrochloride]			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sufentanil			C				Not Reported
	Nimbex			C				Not Reported
	Hypnovel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778446	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2020M1046089			Unknown	FRA

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

Death; Intentional Product Misuse; Off Label Use	Azithromycin	S	Unk		Not Reported
	Plaquenil /00072603/	S	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre- Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235252			Female	CAN

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

Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone	S	Unknown	Actavis
	Alendronate Sodium	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778602	EXPEDITED (15-DAY)		OT	DE-APPCO PHARMA LLC-2083745		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Withdrawal Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778628	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233508		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Azitromicina (7019a)			S				Not Reported

	Hidroxicloroquina (2143a)	S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)	S				Teva
	Doxiciclina (1395a)	S	Oral	100 Mg		Not Reported
	Doxiciclina (1395a)	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778629	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233662		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra			C				Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17779027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Cimzia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 486.0	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	C	Parenteral		Not Reported
	Azathioprine	C	Unknown	1 Every 1 Days	Not Reported
	Ciclosporin	C			Not Reported
	Minocycline	C			Not Reported
	Penicillamine	C			Not Reported
	Phenylbutazone	C			Not Reported
	Prednisolone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17779962	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020189648		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Enoxaparin			S	Subcutaneous	60 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, 1x/Day For 6 Days		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	10 Mg, 1x/Day For 5 Days		Not Reported
	Dexamethasone			S	Intravenous (not	5 Mg, 1x/Day		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780263	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235392		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780744	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046103			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Intentional Product Misuse; Loss Of Consciousness; Off Label Use; Product Use In Unapproved Indication; Ventricular Arrhythmia	Azithromycin			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780898	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1046072		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	800 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17784090	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436771			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Neutropenia	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	18266321	DIRECT					60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Piperacillin-Tazobactam			S		Other Dose:4/0.5 G;	7 DAY	Not Reported
	Lopinavir-Ritonavir			S		Other Dose:400/100 Mg;	7 DAY	Not Reported
	Hydroxychloroquine			S			7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	11271558	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1606866		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown	40 Mg, Unk 3/C G2		Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tocilizumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	12688972	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Contraindicated Product	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

Administered; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Abatacept		S	Unknown	Not Reported
	Cortisone		C	Oral	Not Reported
	Desoximetasone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	15568769	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1700		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Product Use Issue	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Apo-Leflunomide	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16499902	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Arava			S	Oral	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Sulfasalazine			S	Unknown	1000 G, Bid		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	20 Mg		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16645869	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder;	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi

Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava	S		200 Mg, Qd	Sanofi
	Methotrexate	S	Oral	175 Mg, Qw	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16651228	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Enbrel			S				Not Reported
	Actemra			S		8 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16945913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity;	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Depo-Medrol	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16969607	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191008623		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Minocin			S	Unknown			Not Reported

Minocycline	S	Unknown		Not Reported
Myochrysine	S	Subcutaneous		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown	250 Milligram	Not Reported
Rituximab	S	Parenteral		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sirukumab	S	Unknown		Not Reported
Tofacitinib Citrate	S	Oral	10 Milligram	Not Reported
Ustekinumab	S	Subcutaneous		Not Reported
Xeljanz	S	Oral	10 Milligram	Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Methotrexate	C	Unknown	15 Milligram	Not Reported
Methotrexate	C	Unknown	15 Milligram	Not Reported
Prednisone	C	Unknown	5 Milligram	Not Reported
Rheumatrex	C	Unknown		Not Reported
Rheumatrex	C	Unknown	15 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17019418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2458073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Intentional Product Use Issue;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17036319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17261070	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue;	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Solution For Injection	Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

	Diclofenac	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17402847	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020058662		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Drug Withdrawal Syndrome; Hypoaesthesia; Pain; Paraesthesia	Lyrica			S		200 Mg		Pfizer
	Lyrica			S		"300 Mg Twice"		Pfizer
	Sildenafil Citrate			S		"20 Mg Three Times"		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		"200 Mg Twice"		Not Reported
	Trazodone			S		"100 Mg Once"		Not Reported
	Trazodone			S				Not Reported
	Atorvastatin			C		Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Klor-Con			C		Unk		Not Reported
	Lexapro			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17433728	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019025070			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary	Sildenafil			S	Unknown	60 Milligram, Qd		Macleods
	Sildenafil			S	Unknown	30 Milligram, Qd, Film Coated Tablet		Macleods
	Omeprazole 20 Mg			S	Oral	40 Milligram, Qd, 1 Df. 20 Mg Bid		Not Reported
	Omeprazole 20 Mg			S	Oral	20 Milligram, Qd, 1 Df		Not Reported

Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril	S	Oral	2.5 Milligram, Qd, 2 Df	Not Reported
	Ramipril	S	Unknown	5 Milligram, Qd	Not Reported
	Ramipril	S	Oral	1 Dosage Form, Bid	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid, 300 Mg Qd, 1 Df, Tid	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid, 300 Mg Qd, 1 Df, Tid	Not Reported
	Volibris	S	Oral	30 Milligram, Bid	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)	Not Reported
	Quensyl	S	Unknown	40 Milligram, Bid	Not Reported
	Quensyl	S	Unknown	1 Dosage Form, Bid (1-0-0), 20 Mg	Not Reported
	Eliquis	S	Unknown	5 Milligram, Qd, 2 Df Qd, 2.5 Mg Bid	Not Reported
	Eliquis	S	Unknown	1 Dosage Form, Bid	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Bid ((1-0-1))	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd (0 -0 -1)	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Milligram, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17557582	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200318930		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Dermatitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gallbladder Disorder; Groin Pain; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Citalopram			C				Not Reported
	Prednisolone			C				Not Reported
	Gold			C	Unknown			Not Reported
	Pantoloc /01263201/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17721926	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202004003973			Unknown	RUS

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

Asthenia; Blood Pressure Fluctuation; Diarrhoea; Dizziness; Off Label Use; Pneumonia; Pyrexia	Hydroxychloroquine	S	Oral	400 Mg, Bid		Concordia
	Hydroxychloroquine	S	Oral	200 Mg, Bid (Maintaining Dose)		Concordia
	Kaletra	S	Unknown	400 Mg, Bid (Q12h)		Not Reported
	Azithromycin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17742406	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1229778		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S	Unknown	500 Mg		Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported
	Lasix 25 Mg Compresse			C				Not Reported
	Novorapid			C				Not Reported
	Normix			C				Not Reported
	Dobetin			C				Not Reported
	Lantus			C				Not Reported
	Movicol			C				Not Reported
	Deltacortene 25 Mg Compresse			C				Not Reported
	Pantorc 20 Mg Compresse Gastroresistenti			C				Not Reported
	Cardirene 75 Mg			C				Not Reported
	Metoprololo			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17752357	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1044783		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Haloperidol			S	Oral	5 Gtt Drops, Qd		Mylan

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17772419	EXPEDITED (15-DAY)		DE, OT	IT-INCYTE CORPORATION-2020IN004123			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Multiple Organ Dysfunction Syndrome; Respiratory Failure; Sepsis	Inc424			S	Oral	5 Mg, Bid		Incyte
	Inc424			S				Incyte
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	1 Df, Bid		Not Reported
	Prezista			S	Unknown	800 Mg, Qd		Not Reported
	Clexane			S	Unknown	0.6 Ml, Qd (6 Syringe)		Not Reported
	Rocefin			S	Intramuscular	2 G, Qd (1 Bottle)		Not Reported
	Plasil [Metoclopramide Hydrochloride]			C	Intravenous (not otherwise specified)	1 Df, Qd (Inet 5f 2 Ml)		Not Reported
	Albumine Baxter			C	Intravenous (not otherwise specified)	50 G/Ml, Qd (1 Fl, 250 Ml)		Not Reported
	Antra [Omeprazole Magnesium]			C	Intravenous (not otherwise specified)	40 Mg, Qd (Infus, 1 Fl)		Not Reported
	Noradrenalina [Norepinephrine Hydrochloride]			C	Intravenous (not otherwise specified)	4 Ml/H (10 F)		Not Reported
	Ringers Lactate			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	12 Fl (4g+0.500g), Qd		Not Reported
	Oxepa			C	Intravenous (not otherwise specified)	40 Ml/H		Not Reported
	Fluimucil			C	Respiratory (inhalation)	1 Df, Qd (Aer, 10f)		Not Reported
	Vici			C	Intramuscular	1 Df, Qd (5f)		Not Reported
	Eutirox			C	Oral	1 Df, Qd (500cpr, 125 Mcg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778385	EXPEDITED (15-DAY)		OT	RO-AUROBINDO-AUR-APL-2020-024106			Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Sars-Cov-2 Test Positive	Azithromycin			S	Unknown	Unk		Aurobindo
	Kaletra			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778681	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596430		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Surgery; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Therapy Duration: 2.0 Months		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 2.0 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 2.0 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Viread			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778789	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247120		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Metamizol (111a)			S	Intravenous (not otherwise specified)	2 Gram, Every 6 Hours		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778804	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247111		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779033	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2597012		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug	Rituximab			S	Intravenous drip			Not Reported

Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	4.0 Dosage Forms	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779175	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595777		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779238	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247037		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779347	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2020079500		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder	Benlysta Solution For Infusion			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779405	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005272			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Degeneration	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780060	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245719		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Daily		Not Reported
	Clexane			S				Not Reported
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780114	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597489		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780165	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233663		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780193	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233665		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780194	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233691		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	800mg Day (Load) Followed 400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Ivermectina (7778a)			S	Oral	12 Mg Du		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780279	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247122		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Paracetamol			S	Oral	1 Gram, Tid		Ohm Lab
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	25 Mg Cada 8 Horas		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported

	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg ; In Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598582		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780345	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia;	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported

Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Arava	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780437	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594910		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Ebastine			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

Tylenol	C		Not Reported
Vitamin D3	C		Not Reported
Acetaminophen	C		Not Reported
Atacand Plus	C		Not Reported
Bisoprolol Fumarate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780482	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235418		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anorectal Discomfort; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Dyspepsia; Gait Inability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Skin Hyperpigmentation; Treatment Failure	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Fentanyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865689		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 3.0 Months		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Simponi	S	Subcutaneous			Not Reported
Venlafaxine Hydrochloride	S	Oral	Every 1 Day(S)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Hydrodiuril	C	Unknown			Not Reported
M-Eslon	C	Unknown	Capsule, Extended Release		Not Reported
Statex [Morphine Sulfate]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780665	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782195	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication; Therapy Interrupted	Hydroxychloroquine			S	Oral			Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782822	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		9 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782864	DIRECT	Y	DE			72 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		0.93 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782994	EXPEDITED (15-DAY)		OT	NVSC2020US128816			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Mycophenolate Mofetil			S	Transplacental	Unk		Novartis
	Prednisone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Lovenox			S	Transplacental	Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782995	EXPEDITED (15-DAY)		HO, LT, OT	JP-ALVOGEN-2020-ALVOGEN-108377		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Blood	Estradiol			S	Transdermal			Not Reported

Pressure Increased; Caesarean Section; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Uterine Atony; Vaginal Haemorrhage	Tacrolimus	S			Not Reported
	Progesterone	S	Vaginal		Not Reported
	Dydrogesterone	S	Oral		Not Reported
	Prednisolone	S			Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782998	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		5 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17783422	NON-EXPEDITED			US-PFIZER INC-2020192270		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17783531	NON-EXPEDITED			US-PFIZER INC-2020192170		63 YR	Female	USA

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

	Leflunomide			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17783975	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1234425		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Transaminases Increased	Azithromycine Anhydre			S	Oral			Not Reported
	Augmentin			S	Oral	3g		Not Reported
	Plaquenil			S	Oral	200 Mg X 3 Per Day		Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Acupan			C				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784010	DIRECT	Y	OT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		6.42 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784015	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		1.02 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784019	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		8.03 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784026	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003912			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Dopamine			C		Low Dose		Not Reported
	Cardura			C	Oral	8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784110	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005124			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784210	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234252		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not	2 Gr		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784713	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005093			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784740	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234253		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784959	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020191445		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Doxycycline Hyclate			S	Oral	100 Mg, 2x/Day (100 Mg Every 12 Hours)		Pfizer
	Doxycycline Hyclate			S				Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (400 Mg		Not Reported

							Day)			
	Hydroxychloroquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785260	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234538		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785273	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234539		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Sulpirida (3076a)			S	Oral	150 Milligram Daily;		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785276	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234791		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785357	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020187763		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg, 2x/Day		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Metoclopramid [Metoclopramide]			S	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, 4x/Day		Not Reported
	Cefotaxim			C	Intravenous drip	4 G, 2x/Day		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Mg, 1x/Day		Not Reported
	Midazolam			C	Intravenous drip	100 Mg, 1x/Day		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	20 Ug, 4x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785463	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003974			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785480	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1234785		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

	Hidroxicloroquina (2143a)	S				Teva
	Colchicina (142a)	S	Oral	1 Milligram Daily;		Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785486	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		9.81 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234786		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785505	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234790		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Roactemra			S	Intravenous (not	600 Mg		Not Reported

			otherwise specified)			
	Roactemra	S				Not Reported
	Enoxaparina (2482a)	S	Subcutaneous	40 Milligram Daily;		Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785508	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1048030		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	1200 Milligram, Qd, 21.9 Mg/Kg/Day		Not Reported
	Everolimus			C	Unknown	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785570	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785573	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234261		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Topicort	S	Oral		Not Reported
	Topicort	S	Cutaneous		Not Reported
	Leflunomide	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785597	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234474			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Macrobid [Calrithrromycin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786244	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595760			Female	CAN

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

Abdominal Discomfort; Allergic Oedema; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cefazolin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	Therapy Duration: 2.0 Months	Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 2.0 Months	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786577	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1234629		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Azithromycine Anhydre			S	Oral			Not Reported
	Cefotaxime Base			S	Intravenous (not otherwise specified)			Not Reported
	Inexium			S	Intravenous (not otherwise specified)			Not Reported
	Noradrenaline			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported

Loxen [Nicardipine Hydrochloride]	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Oral	Not Reported
Sufentanil	C		Not Reported
Nimbex	C		Not Reported
Hypnovel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786842	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004609			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S				Concordia
	Azithromycin			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786865	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1046344		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S		500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S		400 Milligram, Qd		Mylan
	Lasix /00032601/			C		25 Milligram, Qd		Mylan
	Novorapid			C				Mylan
	Normix			C				Mylan
	Lantus			C				Mylan
	Movicol /01749801/			C				Mylan
	Deltacortene			C				Mylan
	Pantorc			C				Mylan
	Cardirene			C				Mylan
	Metoprololo			C		50 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787004	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020189427		64 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholangiolitis; Hypertransaminasaemia; Off Label Use	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Urbason Solub			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Antra [Omeprazole]			C		Unk		Not Reported
	Clexane			C	Subcutaneous	4000 Kiu		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787014	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235520		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Symbicort Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Polvo			S	Respiratory (inhalation)	6 Dosage Forms Daily; 2-2-2		Not Reported
	Salbutamol			S	Respiratory (inhalation)	6 Dosage Forms Daily; 2-2-2 Inh		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787015	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva

	Prednisone		S	Oral	Actavis
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787017	EXPEDITED (15-DAY)		HO, OT	CA-CELGENEUS-CAN-20200503123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	520 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787018	EXPEDITED (15-DAY)		DS	CA-CELGENEUS-CAN-20200503119		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma	Otezla			S	Unknown	120 Milligram		Celgene
	Otezla			S				Celgene
	Otezla			S				Celgene
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Codeine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Infliximab	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	70 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram	Not Reported
	Remicade	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Benadryl	C	Unknown		Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C	Unknown		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported

Mogadon	C	Oral	5 Milligram		Not Reported
Nitrazepam	C	Unknown	5 Milligram		Not Reported
Prednisone	C	Unknown			Not Reported
Uloric	C	Unknown	160 Milligram		Not Reported
Xeljanz	C	Unknown			Not Reported
Oxycodone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787599	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Mental Disorder; Muscle Injury; Myalgia; Off Label Use; Product Use In Unapproved Indication; Pruritus; Rash	Mycophenolate Mofetil			S	Unknown	3 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787750	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234894		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported

Enbrel	S	Unknown			Not Reported
Arava	S	Unknown	20 Milligram Daily;		Not Reported
Actemra	S	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787778	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235258		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787913	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233963		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Procytox			S	Intravenous (not			Not Reported

			otherwise specified)	
	Arava	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Levofloxacin	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Fentanyl	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17788562	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1046609		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Paracetamol			S	Oral	1gr Cada 8h		Not Reported
	Dexketoprofeno /01363801/			S	Intravenous (not otherwise specified)	25 Mg Cada 8 Horas		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Tocilizumab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17788601	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046601		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17788615	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046603		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd (500 Mg Dia)		Not Reported
	Azithromycin			S				Not Reported
	Metamizol /06276701/			S	Intravenous (not otherwise specified)	2 Gram, Q6h (2gr Cada 6 Horas)		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Milligram, Qd (400 Mg Dia)		Mylan
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, Q8h (1gr Cada 8 Horas)		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790362	EXPEDITED (15-DAY)		OT	CA-009507513-2005CAN004538		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Fosamax			S	Unknown			Merck
	Actemra			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Calcium (Unspecified)			S	Unknown			Not Reported
	Fosinopril Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Formulation: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Synthroid	S	Unknown			Not Reported
	Tylenol	S	Unknown	Unk		Not Reported
	Tylenol	S	Unknown	Unk		Not Reported
	Vitamin D (Unspecified)	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790410	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		5.95 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	18266375	DIRECT		OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S				Not Reported
	Darunavir-Cobicstat			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	18266496	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S				Not Reported
	Darunavir-Cobicistat			S				Not Reported
	Ceftriaxone			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	12441101	EXPEDITED (15-DAY)		OT	CA-ROCHE-1768215		52 YR	Female	CAN

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

Arrhythmia; Arthralgia; Chronic Sinusitis; Diarrhoea; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Off Label Use; Osteoporosis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Inflectra [Infliximab]	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	12715328	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1825208		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	6 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic		Not Reported
	Levothyroxine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Tylenol No.2	S	Unknown		Not Reported
	Ramipril	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Codeine Phosphate	S	Unknown		Not Reported
	Cosopt	C	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	As Required	Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Hydroxychloroquine Phosphate	C	Oral		Not Reported
	Meprobamate	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Tylenol	C			Not Reported
	Phosphoric Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13028484	NON-EXPEDITED			US-PFIZER INC-2016577872		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Diarrhoea; Dyspepsia;	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported

Eructation; Flatulence; Gastrooesophageal Reflux Disease; Malaise; Nervousness; Vomiting	Hydroxychloroquine	S	200 Mg, 2x/Day	Not Reported
	Pravastatin	C	20 Mg, 1x/Day	Not Reported
	Lisinopril	C	10 Mg, 1x/Day	Not Reported
	B6	C	100 Mg, Unk	Not Reported
	B6	C	100 Mg, Unk	Not Reported
	D3	C	1000 Iu, Unk	Not Reported
	Omeprazole	C	20 Mg, 1x/Day (In Morning)	Not Reported
	Docusate Sodium	C	100 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13119773	EXPEDITED (15-DAY)		OT	CA-ROCHE-1880386		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13210436	EXPEDITED (15-DAY)		OT	US-SA-2016SA235895		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Arava			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg,Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg,Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg,Qw		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	5 Mg,Qd		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Infliximab			S	Unknown	300 Mg,Qd		Not Reported
	Pantoprazole			C	Unknown	Unk Unk,Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Atorvastatin			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13704410	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955888			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Marijuana	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S		Not Reported
Xeljanz	S	Oral	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13932807	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017292		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Arava	S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride	C	Oral	50 Mg, Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Xeljanz	C	Oral	50 Mg, Bid		Not Reported
	Rabeprazole Sodium	C	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	15631632	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2018-CA-978035		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S				Teva
	Prednisone			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown	15 Milligram Daily;		Actavis
	Prednisone Acetate			S				Actavis
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	15871101	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004862		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue;	Prednisone			S	Unknown			Actavis

Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Tocilizumab		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	15881000	EXPEDITED (15-DAY)		HO, OT	GR-MYLANLABS-2019M1007066		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Alprazolam			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qw		Not Reported
	Captopril			S	Unknown	Unk		Not Reported
	Captopril			S				Not Reported
	Etanercept			S	Unknown	Unk		Mylan
	Etanercept			S				Mylan
	Folic Acid			S	Unknown	5 Milligram, Qw		Mylan
	Folate Sodium			S	Unknown	5 Milligram, Qw		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Valsartan			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16057413	NON-EXPEDITED			US-PFIZER INC-2019103272		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S				Pfizer

	Sulfasalazine	S	Unk		Pfizer
	Sulfasalazine	S			Pfizer
	Plaquenil	S	Unk		Not Reported
	Plaquenil	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16135292	EXPEDITED (15-DAY)		OT	DE-SA-2018SA251992		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Hydroxychloroquine Sulfate			S	Subcutaneous			Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Plaquenil			S	Oral	2 Df, Qd		Sanofi
	Plaquenil			S	Oral	10 Mg, Qd (5mg Bid)		Sanofi
	Plaquenil			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil			S	Oral	Unk		Sanofi
	Plaquenil			S				Sanofi
	Sulfasalazine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral			Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	20 Mg Tablet		Not Reported
	Methotrexate			S	Oral	20 Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S		20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk, Solution		Not Reported

				Subcutaneous	
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk, Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Unknown	2 Df, Qd, 2ot	Not Reported
	Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	10 Mg, Qd	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16198298	EXPEDITED (15-DAY)		OT	CA-009507513-1904CAN006267		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Fosamax			S	Unknown	Unk		Merck
	Vasotec			S	Unknown			Merck
	Acetazolamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported

Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Iron Polymaltose	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Infliximab	S	Unknown	1 Every 1 Month, Qm	Not Reported
Infliximab	S	Unknown	1 Every 1 Month, Qm	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Cyclophosphamide	S	Unknown		Not Reported
Ferrous Fumarate	S	Unknown		Not Reported
Insulin	S	Unknown		Not Reported
Metformin	S	Unknown		Not Reported
Nutropin (Atropine Sulfate)	S	Subcutaneous	Formulation Liquid	Not Reported
Protropin	S	Intramuscular	Formulation Liquid	Not Reported
Ranitidine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Milligrams, 1 Every 1 Months	Not Reported
Remicade	S			Not Reported
Remicade	S			Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1 Dosage Form; Dosage Form Powder For Solution Intravenous	Not Reported

Remicade	S			Not Reported
Amlodipine	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Testosterone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16226782	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Enbrel			S		Therapy Duration: 366.0		Not Reported
	Orencia			S		Therapy Duration: 365.0		Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16646745	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202640			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic	Plaquenil			S		2 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	2 Df, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported

Product Effect Decreased	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Azathioprine	S	Unknown	Unk, Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	2 Df, Qw	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg, Qd	Not Reported
	Tiaprofenic Acid	C	Unknown	300 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16646786	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202522		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16648293	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202693		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16652291	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Humira			S	Subcutaneous	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

Dexamethasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Enablex [Darifenacin Hydrobromide]	C		Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
Lasix [Furosemide]	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Restasis	C		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C		Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C		Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16655165	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Bacitracin			S				Not Reported
	Methotrexate			S				Not Reported
	Neomycin Sulfate			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Polymyxin B Sulfate			S				Not Reported

	Etanercept	S	Subcutaneous		Not Reported
	Prednisone	C	Intramuscular		Not Reported
	Xeljanz	C	Oral	2 Df, Bid, 5mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16656988	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202955		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Arava			S		1 Df, Qd		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Sulfasalazine			S		1500 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16716102	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Blood Cholesterol Increased; Bone Erosion; Bronchitis; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Cirrhosis; Hypertension; Infection; Joint Dislocation; Joint Stiffness; Malaise; Nasopharyngitis; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Psoriasis; Synovitis; Tachycardia; Upper Respiratory Tract Infection	Minocycline Hydrochloride	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Telmisartan	S	Unknown		Not Reported
	Zopiclone	S	Unknown		Not Reported
	Amlodipine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Amitriptyline	C	Oral		Not Reported
	Betamethasone	C	Topical		Not Reported
	Betamethasone Dipropionate W/Calcipotriol	C	Unknown		Not Reported
	Melatonin	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16957606	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2019-CA-1125473		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Disseminated Varicella Zoster Vaccine Virus Infection; Gastrointestinal Disorder; Leukopenia; Lung Disorder; Multiple Organ Dysfunction Syndrome; Thrombocytopenia	Methotrexate			S	Unknown	2.5 Milligram Daily; Administered 6 Days A Week; Ongoing For 3 Years		Barr
	Prednisone			S	Unknown	10 Milligram Daily; Tapered One Month Prior To Presentation		Actavis
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Zostavax Ii			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16971655	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191006447			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Otezla			S	Oral	60 Milligram		Celgene
	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown	150 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			C	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17026290	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459593		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Platelet Count Decreased; Rhinorrhoea; Skin Mass	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration 5.0 Month(S)		Not Reported
	Methotrexate			S	Unknown	Therapy Duration 4.0 Month(S)		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	Therapy Duration -229.0		Not Reported
	Morphine			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17303675	EXPEDITED (15-DAY)		DE	CA-009507513-2001CAN007751		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Fosamax			S	Unknown	70 Milligram, 1 Every 1 Weeks		Merck
	Flovent			S	Unknown	Dosage Form: Not Specified, Unk		Not Reported

	Albuterol Sulfate (+) Ipratropium Bromide	S	Unknown	Dosage Form: Solution Inhalation, Unk	Not Reported
	Lasix (Furosemide Sodium)	S	Unknown	40 Milligram, Unk; Dosage Form: Not Specified	Not Reported
	Lipitor	S	Unknown	10 Milligram, Unk; Dosage Form: Not Specified	Not Reported
	Losec (Omeprazole Magnesium)	S	Oral	20 Milligram, Unk; Dosage Form: Not Specified	Not Reported
	Metformin	S	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
	Nitrazadon	S	Unknown	10 Milligram, Unk	Not Reported
	Plaquenil	S	Unknown	300 Milligram, 1 Every 1 Days	Not Reported
	Prednisone	S	Unknown	5 Milligram,1 Every 1 Days, Dosage Form: Not Specified	Not Reported
	Salmeterol Xinafoate	S	Unknown	Unk	Not Reported
	Tylenol	S	Unknown	500 Milligram, Unk; Dosage Form: Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17570987	NON-EXPEDITED			US-PFIZER INC-2020121578		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, 0, 2, 6 Wks, Then Every 8 Wks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 7 Weeks		Not Reported

Humira	S	Unk	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Otrexup	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17663764	EXPEDITED (15-DAY)		OT	US-ROCHE-2580025			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Dreams; Alopecia; Anaemia; Cytopenia; Depressed Mood; Dizziness; Dry Mouth; Fatigue; Gastrointestinal Disorder; Hirsutism; Infection; Insomnia; Leukopenia; Palpitations; Transaminases Increased	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17678874	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002607			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bronchopulmonary Aspergillosis; Catheter Bacteraemia; Off Label Use; Pneumomediastinum; Pneumonia Bacterial; Pneumonia Bacterial; Renal Failure; Shock Haemorrhagic	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Heparine			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17726960	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004004250			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chondrocalcinosis; Off Label Use; Systemic Inflammatory Response Syndrome	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		400 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17727561	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1042619		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Lasilix /00032601/			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Mylan
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Mylan
	Noradrenaline /00127501/			C	Intravenous (not otherwise specified)	Unk		Mylan
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Mylan
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Qd		Mylan
	Transipeglib			C	Oral	Unk		Mylan
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Mylan
	Nimbex /01302502/			C	Intravenous (not otherwise specified)	Unk		Mylan

	Ultibro Breezhaler	C	Respiratory (inhalation)	Unk		Mylan
	Seresta	C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17736227	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1043094		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Levofloxacin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Tacrolimus			S		Unk		Mylan
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Mylan
	Ceftriaxona /00672201/			C	Unknown	Unk		Mylan
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd		Mylan
	Prednisona			C	Oral	20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17766483	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020185574		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17782613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593919		71 YR	Female	CAN

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

Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S		Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17787749	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-15795		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-	Infliximab			S	Oral	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported

Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Alendronic Acid	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Unknown	Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apremilast	S	Unknown	Unknown	Not Reported
	Apremilast	S	Unknown		Not Reported
	Apremilast	S			Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown	Not Reported
	Cyclosporin	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Motrin [Ibuprofen]	S	Oral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Subcutaneous	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported

Stelara	S	Subcutaneous	Unknown		Not Reported
Sulfasalazine	S	Endocervical			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Codeine	S	Unknown	Unknown		Not Reported
Otezla	S	Unknown	Unknown		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unknown		Not Reported
Colchicine	C	Oral	Unknown		Not Reported
Dexilant	C	Oral	Unknown		Not Reported
Febuxostat	C	Unknown	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported
Gravol	C	Unknown	Unknown		Not Reported
Mogadon	C	Oral			Not Reported
Nitrazepam	C	Unknown			Not Reported
Oxycodone	C	Unknown	Unknown		Not Reported
Prednisolone	C	Unknown			Not Reported
Prednisolone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Uloric	C	Unknown			Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788081	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-024673		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Quetiapine Arrow Lp 50 Mg Prolonged Release Tablet			S	Oral	100 Milligram, Once A Day		Aurobindo
	Zithromax			S	Oral	250 Milligram, Once A Day		Not Reported

	Plaquenil		S	Oral	600 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788113	EXPEDITED (15-DAY)		HO	ES-ACCORD-181994		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597595		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596424		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Prednisone		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788436	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020192176		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fall; Gait Inability; Malaise; Paralysis; Spinal Fracture	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234906		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication;	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Barr
	Methotrexate			S	Subcutaneous	25 Milligram		Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown	7.5 Milligram		Actavis
	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis; Synovitis	Dilaudid	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17789376	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247219		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17790293	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001539			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Dysphagia; Musculoskeletal Toxicity; Myopathy Toxic; Toxicity To Various Agents; Weight Decreased	Chloroquine			S	Unknown	200 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Acetylsalicylic Acid			C	Unknown	75 Milligram, Qd		Not Reported
	Clopidogrel			C	Unknown	75 Milligram, Qd		Not Reported
	Fenofibrate			C	Unknown	100 Milligram, Qd		Not Reported
	Ranitidine			C	Unknown	300 Milligram, Qd		Not Reported
	Clobetascol			C	Unknown	Unk, Qd		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

	Tramadol		C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791337	EXPEDITED (15-DAY)		HO, OT	FR-SA-2020SA125110		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Ventricular Fibrillation	Plaquenil			S	Oral			Sanofi
	Plaquenil			S				Sanofi
	Lasilix			S	Oral	Unk		Sanofi
	Risordan			S	Intravenous (not otherwise specified)			Not Reported
	Irbesartan			S	Oral	Unk		Sanofi
	Carvedilol			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791355	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001382			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles; Palpitations	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791635	EXPEDITED (15-DAY)		OT	ES-ACCORD-182005		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791638	EXPEDITED (15-DAY)		OT	GB-ACCORD-181984		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles; Palpitations	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791654	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234484		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S				Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791682	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046807		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg Dia		Not Reported

	Dolquine	S	Oral	400 Mg Dia	Mylan
	Kaletra	S	Oral	2u / 12 H	Mylan
	Kaletra	S			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791698	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1234911		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown	14 Milligram Daily;		Not Reported
	Dilaudid			C	Unknown	12 Milligram Daily;		Not Reported
	Furosemide			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown	54 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791711	EXPEDITED (15-DAY)		OT	ES-ACCORD-181713		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg / 12h From 14-Apr-2020 To 17-Apr-2020		Not Reported
	Ceftriaxone			S	Intravenous (not	2gr/24h		Not Reported

				otherwise specified)			
	Hydroxychloroquine		S	Oral	400 Mg / 24 H From 11-Apr-2020 To 12-Apr-2020, 400 Mg / 12 H From 14-Apr-2020 To 17-Apr-2020		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595998		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Subcutaneous			Not Reported
	Zostavax			C	Subcutaneous	Powder For Suspension Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791733	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597016		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Caffeine			C				Not Reported
	Arava			C				Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791743	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-15914			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis;	Infliximab			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Unknown	Unknown		Not Reported

Therapeutic Product Effect Incomplete	Acidophilus	C	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Deflazacort	C	Unknown	Unknown	Not Reported
	Dilaudid	C	Unknown	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
	Januvia	C	Unknown	Unknown	Not Reported
	Kenalog	C	Unknown	Unknown	Not Reported
	Lidocaine	C	Topical	Unknown	Not Reported
	Metronidazole	C	Unknown	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Unknown	Not Reported
	Pantoloc	C	Unknown	Unknown	Not Reported
	Pregabalin	C	Unknown	Unknown	Not Reported
	Risedronate	C	Unknown	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported
	Salbutamol	C	Unknown	Unknown	Not Reported
	Triamcinolone	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791808	DIRECT	Y	LT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral			Sandoz
	Acetaminophen 650 Mg Po			C				Not Reported
	Maalox-Plus 30 Ml Po			C				Not Reported
	Albuterol Mdi			C				Not Reported
	Enoxaparin 40mg Sc			C				Not Reported
	Levofloxacin 750mg Po			C				Not Reported
	Melatonin 3mg			C				Not Reported

	Ondansetron 4mg Ivp	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792081	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202004005069			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epstein-Barr Virus Infection Reactivation; Klebsiella Infection; Off Label Use; Pneumonia Adenoviral; Pneumonia Escherichia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Cyclophosphamide			S	Unknown	14.5 Mg/Kg Days -6 And -5		Not Reported
	Cyclophosphamide			S	Unknown	500 Mg/Kg Days 3 And 4		Not Reported
	Fludarabine Phosphate			S	Unknown	30 Mg/M2 From Days -6 Through -2		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S				Not Reported
	Mesalazine			S	Unknown	1.2 G, Bid Q12h		Not Reported
	Mesalazine			S				Not Reported
	Azathioprine			S	Unknown	150 Mg, Qd		Not Reported
	Azathioprine			S				Not Reported
	Busulfan			S	Intravenous (not otherwise specified)	Unk, Qd On Days -4, -3,-2		Not Reported
	Sirolimus			S	Unknown	Unk		Not Reported
	Basiliximab			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792157	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234794		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva

	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 G, Day	Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792348	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020192350		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, 1x/Day		Not Reported
	Novorapid			C				Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C				Not Reported
	Cardirene			C		75 Mg		Not Reported
	Pantorc			C		20 Mg		Not Reported
	Lantus			C				Not Reported
	Metoprololo			C		50 Mg		Not Reported
	Dobetin [Cyanocobalamin]			C				Not Reported
	Normix			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Deltacortene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792351	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235702			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Adverse Event Reporting System
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Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acidophilus			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Unknown			Not Reported
	Metronidazole			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported

	Risedronate	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported
	Triamcinolone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792663	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233509		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Rapamune			C	Oral	1 Mg		Not Reported
	Rapamune			C				Not Reported
	Enoxaparina (2482a)			C	Subcutaneous	40 Mg Day		Not Reported
	Deflazacort (2546a)			C	Oral	6 Mg		Not Reported
	Deflazacort (2546a)			C				Not Reported
	Deflazacort (2546a)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792744	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020191417		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792762	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020191421		49 YR	Male	ESP

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

Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin	S	Oral	500 Mg, Daily		Pfizer
	Azithromycin	S				Pfizer
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported
	Ceftriaxone	S				Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792773	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020191268		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Off Label Use; Product Use In Unapproved Indication; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Pfizer
	Noradrenaline Hospira			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium [Esomeprazole Magnesium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	Unk		Not Reported
	Loxen [Nicardipine Hydrochloride]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Nimbex [Cisatracurium Besilate]			C		Unk		Not Reported
	Hypnovel [Midazolam Hydrochloride]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793017	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi

Treatment Failure	Leflunomide	S	Unknown		Sanofi
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Enbrel	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793233	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234720		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Xeljanz		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234471			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate			S	Intra-arterial	25 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793974	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234505		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Visual Impairment	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Macrobid [Clarithromycin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794208	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1047539			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Qd		Mylan
	Oxygen			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794230	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2020M1047544			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Prednisolone			S	Transplacental	Unk		Not Reported
	Certolizumab			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan
	Sulfasalazine			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794256	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1047894		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Metilprednisolona /00049601/			S	Intravenous (not otherwise specified)	250 Milligram, Qd		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram, Qd		Mylan
	Dolquine			S	Oral	200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794348	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1047857		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd 2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Tocilizumab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794351	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2020M1047666		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Trazodone			S	Oral	1 Dosage Form, Qd (1 Df, Qd , 1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The)		Not Reported
	Olanzapine			S	Oral	1 Dosage Form, Qd (1 Df Qd, 1/2 Tablet 2x/Day, Treatment Was Suspended For 2 Days 11/04 And 12/04)		Mylan
	Plaquenil /00072603/			S	Oral	Unk (Day 1: 400mg 2x/D; Day 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg; 08/04 To 10/04)		Mylan
	Clexane			C		Unk		Mylan
	Perindopril			C		1 Dosage Form, Qd (1 Df, Qd)		Mylan
	Movicol /01749801/			C		1 Dosage Form, Qd (1 Df, Qd)		Mylan
	L-Thyroxine /00068001/			C		1 Dosage Form, Qd (1 Df, Qd)		Mylan
	Metformin			C		2 Dosage Form, Qd (2 Df, Qd)		Mylan
	Prolopa			C		0.5 Dosage Form, Qd (0.5 Df, Qd)		Mylan
	Contramal			C		1 Dosage Form, Prn (As Necessary)		Mylan
	Kalium /00031401/			C	Oral	Unk		Mylan
	Algostase Mono			C		3 Dosage Form, Qd (3 Df, Qd)		Mylan
	Pradaxa			C		Unk		Mylan
	Uni Diamicron			C		60 Milligram, Bid (60 Mg, Bid)		Mylan
	Magnetop /00434501/			C	Oral	450 Milligram, Qd (450 Mg, Qd)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794561	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Pain; Skin Irritation; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794844	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234509			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794857	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-014019		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal	Dexametasona			S	Intravenous (not	20 Mg Dia		Bausch And Lomb

Haemorrhage; Vessel Puncture Site Haemorrhage			otherwise specified)			
	Enoxaparina	S	Subcutaneous			Not Reported
	Hidroxicloroquina	S	Oral			Not Reported
	Acetylsalicylate Lysine	S	Intravenous (not otherwise specified)	200 Mg, One Total		Not Reported
	Adiro	S	Oral	500 Tablets,1 Cp Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794860	EXPEDITED (15-DAY)		OT	US-SA-2020SA122902		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Lupus Nephritis; Off Label Use; Proteinuria; Treatment Noncompliance	Hydroxychloroquine			S				Sanofi
	Prednisone			S				Not Reported
	Lovenox			S				Sanofi
	Sulfamethoxazole/Trimethoprim			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S				Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123326		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Arava			S		Unk		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Lantus			C	Subcutaneous	Unk		Not Reported

Lozide [Gliclazide]	C	Unk		Not Reported
Metformin	C	Unk		Not Reported
Naproxen	C	Unk		Not Reported
Prednisone	C	Unk		Not Reported
Ramipril	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122626		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794883	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123045		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Leflunomide			S	Unknown	2 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794893	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234722		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Prednisone			S	Unknown	2.5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab/Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Humira			C	Unknown			Not Reported
	Indapamide			C	Oral	1.25 Milligram Daily;		Not Reported
	Naproxen			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Pantoloc [Pantoprazole]			C	Oral	40 Milligram Daily;		Not Reported
	Perindopril			C	Unknown	2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794900	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234926		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	40 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17795162	EXPEDITED (15-DAY)		DE, OT	ES-BAUSCH-BL-2020-014022		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Dexametasona			S	Intravenous (not otherwise specified)			Bausch And Lomb
	Dexametasona			S	Intravenous (not otherwise specified)	Dose Reduced		Bausch And Lomb
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg In Total		Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparina			S	Subcutaneous			Not Reported
	Enoxaparina			S	Subcutaneous	Dose Reduced		Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17795175	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020195127		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17795257	EXPEDITED (15-DAY)		HO, LT, OT	JP-INSUD PHARMA-2004JP00069			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Off Label Use; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Progesterone			S	Vaginal	300 Mg		Xiromed
	Estrasorb			S	Transdermal			Exceltis Usa
	Tacrolimus Monohydrate			S	Unknown	4 Mg		Not Reported
	Dydrogesterone			S	Oral	15 Milligram Daily		Not Reported
	Prednisolone			S	Unknown	7.5 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797261	DIRECT	Y	LT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	Other Frequency:Bid X 1day,Then Qd;		Sandoz
	Acetaminophen 325 Mg			C				Not Reported
	Azithromycin 250 Mg			C				Not Reported
	Baclofen 20mg			C				Not Reported
	Doxazocin 6mg			C				Not Reported

Famotidine 40mg	C		Not Reported
Finasteride 5mg	C		Not Reported
Furosemide 40mg	C		Not Reported
Milk Of Magnesia 30ml	C		Not Reported
Rivaroxaban 20mg	C		Not Reported
Senna Tab 17.2mg	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797621	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797861	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797867	DIRECT	Y				86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Cerebrovascular Accident; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Respiratory Failure; Troponin Increased	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797872	DIRECT	Y				84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Haemoglobin Decreased	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797909	DIRECT	Y				82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17687239	EXPEDITED (15-DAY)		DE, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244297		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligrams, Daily		Sun
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	()		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	()		Not Reported
	Perfalgan 10 Mg/Ml, Solution Pour Perfusion			C	Intravenous (not otherwise specified)	()		Not Reported
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)	()		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	()		Not Reported

Tazocilline	C	Intravenous (not otherwise specified)	4 Dosage Form, Daily		Not Reported
Transipeg	C	Oral	()		Not Reported
Potassium (Chlorure De)	C	Intravenous (not otherwise specified)	()		Not Reported
Effexor L.P. 37,5 Mg, Gelule A Liberation Prolongee	C	Oral	Unk		Not Reported
Ultibro Breezhaler	C	Respiratory (inhalation)	Unk		Not Reported
Seresta 10 Mg, Comprime	C	Oral			Not Reported
Rocephine	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17703365	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-019744		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Overdose; Oxygen Saturation Decreased; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Paracetamol			S	Other	4 Gram, Once A Day		Aurobindo
	Paracetamol			S				Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	800 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	1200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	600 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	1000 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	400 Milligram, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	0.6 Milliliter, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	0.7 Milliliter, Once A Day		Not Reported
	Dexamethasone			C	Intravenous (not	20 Milligram, Once A Day		Not Reported

			otherwise specified)		
	Movicol	C	Other	2 Dosage Form, Once A Day	Not Reported
	Movicol	C			Not Reported
	Lasilix	C	Parenteral	40 Milligram, Once A Day	Not Reported
	Pantoprazole	C	Oral	40 Milligram, Once A Day	Not Reported
	Pantoprazole	C			Not Reported
	Lantus	C	Subcutaneous	20 International Unit, Once A Day	Not Reported
	Tienam	C	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17727385	EXPEDITED (15-DAY)		DE, HO, OT	SK-ACCORD-180080		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Methotrexate			S		Unk		Accord
	Mycophenolic Acid			S				Accord
	Azathioprine/Azathioprine Sodium			S		Unk		Not Reported
	Belimumab			S		Unk		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17764120	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246394		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Sudden Death	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Milligram, 1dose/6hour		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram, Bid		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Milligram, Tid		Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)	()		Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)	20 Microgram, 1dose/6hour		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	Unk		Not Reported
	Cefotaxima (3840a)			C	Intravenous drip	4 Gram, Bid		Not Reported
	Midazolam (2256a)			C	Intravenous drip	100 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	600 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791594	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050907			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram Every 8 Hours		Not Reported
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S				Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab	S				Not Reported
	Paracetamol	S	Oral	1 Gram Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791595	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050817			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S				Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	2u Cada 12h		Not Reported
	Lopinavir/Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791597	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050909			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791598	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050908			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 Gram Every 6 Hours		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794272	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234955		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Day		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794307	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234956		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794360	EXPEDITED (15-DAY)		HO, LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247339		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Metilprednisolona (888a)			S	Intravenous (not otherwise specified)	250 Milligrams, Daily		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Compri...			S	Oral	2 Dosage Form, Bid		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram, Daily		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	200 Milligram, Bid		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	560 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794502	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050853			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg		Zydus Pharm
	Dolquine			S	Oral	400 Mg		Not Reported

	Kaletra	S	Oral	2 Dosage Form		Not Reported
	Kaletra	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794877	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234795		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795605	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050808			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg		Zydus Pharm
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795606	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050813			Unknown	ESP

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

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Mg		Zydus Pharm
	Ceftriaxona [Ceftriaxone]	S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Ceftriaxona [Ceftriaxone]	S				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795681	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2020-15879		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Ferrous Fumarate			S	Unknown	Unknown		Not Reported
	Ferrous Fumarate W/Folic Acid			S	Unknown	Unknown		Not Reported
	Ferrous Fumarate W/Folic Acid			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Naprosyn [Naproxen]	S	Oral		Not Reported
Naprosyn [Naproxen]	S	Oral		Not Reported
Naprosyn [Naproxen]	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Palafer	S	Unknown	Unknown	Not Reported
Palafer Cf	S	Unknown	Unknown	Not Reported
Pantoloc	S	Unknown		Not Reported
Pantoloc	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported

Pantoprazole Sodium	S	Unknown			Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown			Not Reported
Pantoprazole Teva	S	Unknown			Not Reported
Pantoprazole Teva	S	Unknown	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Remicade	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Oral			Not Reported
Celebrex	C	Oral			Not Reported
Celecoxib	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795759	EXPEDITED (15-DAY)		OT	GB-ACCORD-181478		41 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Febrile Convulsion; Generalised Tonic-Clonic Seizure	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795794	EXPEDITED (15-DAY)		OT	NVSC2020GB130263		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalitis; Immune Thrombocytopenia; Liver Function Test Abnormal; Pleurisy; Systemic Lupus Erythematosus	Azathioprine			S	Unknown	150 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisolone			S	Unknown	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795850	EXPEDITED (15-DAY)		OT	ES-ACCORD-182145		43 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Paracetamol			S	Oral	1gr Every 8 Hours		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795851	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-180063		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Sudden Death	Tacrolimus			S	Oral			Accord
	Levofloxacin/Levofloxacin Mesylate			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Ceftriaxone/Ceftriaxone Sodium			C	Unknown			Not Reported
	Enoxaparin			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795856	EXPEDITED (15-DAY)		OT	SI-ACCORD-182063		50 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg 15.4. In The Evening And 16.4 In The Morning 400 Mg, Then 200 Mg/12 H		Not Reported
	Daleron			S	Oral	500 Mg; As Necessary, Dotal Dose Of 2 Tbl On		Not Reported

				14. And 15.4.		
	Fragmin	S	Subcutaneous	5000, 5000/24 Ur		Not Reported
	Pantoprazol Teva	C	Oral	20 Mg; 20 Mg/Day		Not Reported
	Folkodin Alkaloid-Int	C	Oral	10 Mg; As Necessary 2caps/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795927	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050898			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Zydus Pharm
	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram		Not Reported
	Prednisona			C	Oral			Not Reported
	Enoxaparina Sodica			C	Subcutaneous			Not Reported
	Ceftriaxona [Ceftriaxone]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795960	EXPEDITED (15-DAY)		DE, OT	FR-MALLINCKRODT-T202002262		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Diarrhoea; Hepatocellular Injury	Ofirmev			S	Intravenous (not otherwise specified)	4 Gram, Qd		Mallinckrodt
	Linezolide Kabi			S	Intravenous (not otherwise specified)	1200 Milligram, Qd		Not Reported
	Rovamycine			S	Intravenous (not otherwise specified)	4.5 Mega-International Unit, Qd		Not Reported
	Plaquenil			S	Oral	600 Milligram, Qd		Not Reported

	Cefotaxime		S	Intravenous (not otherwise specified)	6 Gram, Qd	Not Reported
	Movicol Plain		C	Unknown	Unk	Not Reported
	Amikacine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17629401	NON-EXPEDITED			US-AMGEN-USASP2020048450		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, 0, 2, 6 Wks, Then Every 8 Wks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 7 Weeks		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Otrexup			S	Unknown	Unk		Not Reported
	Otrexup			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17691077	EXPEDITED (15-DAY)		HO	CA-ROCHE-2584754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulphate	S	Oral	Not Reported
	Cimzia	C	Subcutaneous	Not Reported
	Enbrel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17796047	EXPEDITED (15-DAY)		HO, LT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050911			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Methylprednisolone			S	Intravenous (not otherwise specified)	250 Milligram		Not Reported
	Kaletra			S	Oral	2 Dosage Form		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Dolquine			S	Oral	200 Milligram		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17796048	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050934			Unknown	ESP

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

Bradycardia; Long Qt Syndrome	Azithromycin	S	Unknown	Unk	Zydus Pharm
	Propofol	S	Unknown	Unk	Not Reported
	Propofol	S			Not Reported
	Dolquine	S	Oral	200 Milligram	Not Reported
	Midazolam	S	Unknown		Not Reported
	Midazolam	S			Not Reported
	Kaletra	S	Oral	Unk	Not Reported
	Ceftriaxona [Ceftriaxone]	S	Unknown	Unk	Not Reported
	Omnic Ocas	C	Unknown		Not Reported
	Simvastatina	C	Unknown		Not Reported
	Cortica	C	Unknown	Corticoides A Dosis Bajas	Not Reported
	Kalpress	C	Unknown	Unk	Not Reported
	Manidon Hta	C	Unknown	Unk	Not Reported
	Rilast	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17796127	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235371			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	11042903	EXPEDITED (15-DAY)		OT	CA-ROCHE-1565162		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 990.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Tramadol Hcl			C	Oral			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	12974330	EXPEDITED (15-DAY)		OT	CA-ROCHE-1858733			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13011431	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865032		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Increased; Urticaria	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 486.0 Nos	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported
	Penicillamine	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Tocilizumab	C	Unknown		Not Reported
	D-Penicillamine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13045102	EXPEDITED (15-DAY)		OT	CA-ROCHE-1869641		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Enbrel	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Folinic Acid	C	Unknown	Not Reported
	Apo-Hydroxyquine	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Leucovorin [Folinic Acid]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13132261	EXPEDITED (15-DAY)		OT	CA-ROCHE-1619414		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 987 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Lyrica	S	Oral		Not Reported
	Xeljanz	S	Oral	Therapy Duration: 2 Years	Not Reported
	Xeljanz	S	Oral	Therapy Duration: 3 Months	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Arava	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13316486	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808908			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	14058071	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182819		54 YR	Female	CAN

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

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Plaquenil	S	Oral	200 Mg,Bid	Sanofi
	Arava	S	Oral	20 Mg,Qd	Sanofi
	Hydroxychloroquine Sulfate	S		200 Mg, Bid	Sanofi
	Leflunomide	S	Unknown	20 Mg, Qd	Sanofi
	Leflunomide	S		20 Mg, Qd	Sanofi
	Paracetamol	S	Unknown	Unk Unk,Prn	Not Reported
	Paracetamol	S			Not Reported
	Paracetamol	S		325 Mg	Not Reported
	Sulfasalazine	S	Oral	2000 Mg,Unk	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S			Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	50 Mg,Qw	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia	S		Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Tylenol	C			Not Reported
	Codeine Phosphate	C	Unknown	Unk Unk,Unk	Not Reported
	Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
	Celebrex	C	Oral	200 Mg,Bid	Not Reported
	Hydromorphone Hcl	C			Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Hydromorph	C	Unknown	Unk Unk,Prn	Not Reported
	Methotrexate	C	Unknown	25 Mg,Qw	Not Reported
	Synthroid	C		Unk Unk,Unk	Not Reported
	Meloxicam	C		Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	14165914	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210506		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Arava			S	Oral	20 Mg,Qd		Sanofi
	Paracetamol			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg,Bid		Sanofi
	Paracetamol			S		325 Mg		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	25 Mg/Ml, Qw		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk, Unk		Not Reported
	Synthroid			C		Unk Unk,Unk		Not Reported
	Tylenol [Paracetamol]			C				Not Reported
	Leflunomide			C	Unknown	20 Mg, Qd		Not Reported
	Celebrex			C				Not Reported
	Hydromorphone Hcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	16005011	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA139124		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk Unk,Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Humira			C	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	16438452	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15073			Female	CAN

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

Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Etanercept	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous, Single-Use Pre-Filled Syringe	Not Reported
	Desoximetasone	S	Unknown	Unknown	Not Reported
	Desoximetasone	S	Oral	Unknown	Not Reported
	Folic Acid	S	Unknown	Unknown	Not Reported
	Folic Acid	S			Not Reported
	Fosamax	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown, Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution	Not Reported

				Subcutaneous		
	Simponi	S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown		Not Reported
	Enbrel	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unknown		Not Reported
	Cetirizine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	16936539	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436270		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

			otherwise specified) Intravenous		
	Humira	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17063576	EXPEDITED (15-DAY)		HO	CA-ROCHE-2472424			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17070136	EXPEDITED (15-DAY)		HO	CA-ROCHE-2474304			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

White Blood Cell Count Decreased	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17258667	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513921		55 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17755163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592591		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown	7.0 Months		Not Reported
	Adalimumab			S	Unknown	9.0 Years		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17790725	EXPEDITED (15-DAY)		DE, OT	IT-ABBVIE-20K-083-3402967-00		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Hypertransaminasaemia; Off Label Use; Septic Shock	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796746	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122659		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis	Arava			S				Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S		40 Mg		Not Reported
	Orencia			S		125 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi			C	Subcutaneous	50 Mg, Qm		Not Reported
	Prednisone			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796747	EXPEDITED (15-DAY)		OT	ES-SA-2020SA124226		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Enoxaparin Sodium			S	Subcutaneous	80 Mg		Sanofi
	Enoxaparin Sodium			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg		Not Reported

	Dexamethasone		S	Unknown	Unk	Not Reported
	Azithromycin		S	Oral	500 Mg Day	Not Reported
	Ceftriaxone		S	Intravenous (not otherwise specified)	2 Gr Day	Not Reported
	Roactemra		S	Intravenous (not otherwise specified)	600 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796759	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796995	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Off Label Use; Weight Increased	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Levothyroxine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Rituximab			S	Intravenous drip	Therapy Duration: 403.0 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 0.0		Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous	Therapy Duration: 8.0 Years		Not Reported
	Imuran [Azathioprine]			S	Unknown	Therapy Duration: 21.0 Years		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 31.0		Not Reported
	Glyburide			C	Oral			Not Reported
	Infliximab			C	Unknown			Not Reported
	Lipitor [Atorvastatin Calcium]			C	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797182	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

Acetaminophen	S	Unknown		Not Reported
Propofol	S	Unknown		Actavis
Cimzia Single-Use Prefilled Syringe	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797231	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600590		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797302	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004004827			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation; Mechanical Ventilation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797559	EXPEDITED (15-DAY)		OT	NVSC2020PH132416		80 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Suspected Covid-19	Azithromycin			S	Oral	0.5 Df (250 Mg), Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797999	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247406		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Azithromycin			S	Unknown	Unk		Sun
	Kaletra			S	Unknown	Unk		Not Reported
	Interferon Beta-1b (2305od)			S	Unknown	Unk		Not Reported
	Ceftriaxona (501a)			S	Unknown	Unk		Not Reported
	Hidroxicloroquina (2143a)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798034	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598836		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798156	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1228873		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported

	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798212	EXPEDITED (15-DAY)		DE	ES-BAUSCH-BL-2020-014076		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Dia		Bausch And Lomb
	Enoxaparina			S	Subcutaneous	40mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Total Dose: 600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Dexketoprofeno			S	Intravenous (not otherwise specified)	25 Mg Every 8 Hours		Not Reported
	Hidroxicloroquina			S	Oral	400 Mg Dia		Not Reported
	Azitromicina			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798226	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235250			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798348	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503968			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798480	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1235771		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema	Darunavir			S	Oral	1 Dosage Forms		Teva
	Colchicina Lirca			S	Oral	1 Dosage Forms		Not Reported
	Plaquenil			S		2 Dosage Forms		Not Reported
	Ritonavir Sandoz			S	Oral	1 Dosage Forms		Not Reported
	Clexane			C				Not Reported
	Pradaxa 150mg Hard Capsules			C				Not Reported
	Lasix 25 Mg Compresse			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Zopranol			C	Oral			Not Reported
	Cordarone 200 Mg Compresse			C				Not Reported
	Omeprazole			C				Not Reported
	Enoxaparin Sodium			C	Subcutaneous	4000 Ku		Not Reported
	Symbicort, 160 Microgrammi/4,5 Microgrammi/ Inalazione, Polvere Per In			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798528	EXPEDITED (15-DAY)		HO	FR-NATCO PHARMA-2020NAT00018		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Musculoskeletal Toxicity	Chloroquine Phosphate			S	Unknown	200 Mg, 1x/Day		Natco Pharma
	Hydroxychloroquine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	75 Mg, 1x/Day		Not Reported
	Clopidogrel			C	Unknown	75 Mg, 1x/Day		Not Reported
	Fenofibrate			C	Unknown	100 Mg, 1x/Day		Not Reported
	Ranitidine			C	Unknown	300 Mg, 1x/Day		Not Reported
	Clobetasol			S	Unknown	1 Application/Day		Not Reported
	Paracetamol/Tramadol			C	Unknown	If Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798599	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235508		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Pulmonary Embolism	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Azitromicina (7019a)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798652	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122868		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Hydroxychloroquine			S	Subcutaneous	Unk		Sanofi
	Methotrexate			S	Oral	20 Mg		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S		3 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798666	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1047766		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798848	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235389		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Piroxicam			S	Unknown			Not Reported
	Pregabalin			S	Oral			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab/Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798851	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2020-ES-1235527		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Linezolid (1279a)			S	Intravenous (not otherwise specified)	1200 Milligram Daily;		Teva
	Piperacilina Tazobactam 4g/0,5g			S	Intravenous (not otherwise specified)	1 Dosage Form, C/8h		Not Reported
	Roactemra 20 Mg/Ml, Concentrado Para Solucion Para Perfusion			S		600mg		Not Reported
	Roactemra 20 Mg/Ml, Concentrado Para Solucion Para Perfusion			S				Not Reported
	Meropenem (7155a)			S	Intravenous (not otherwise specified)	3 Gram Daily;		Not Reported
	Metamizol (111a)			S	Intravenous (not otherwise specified)	6 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235812		34 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798978	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235384		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799003	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-2019800US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Fosfomycin Tromethamine - Bp			S	Oral	3 G, Qd		Allergan
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported
	Azitromicina			S				Not Reported
	Cefixima			S	Oral	400 Mg, Qd		Not Reported
	Hidroxicloroquina			S	Oral	400 Mg, Qd		Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799007	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235779		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Paracetamol (12a)			S	Oral	3 Gram Daily; 1gr Every 8 Hours		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Cefditoreno Pivoxilo (7358ps)			S	Oral	800 Milligram Daily; 400 Mg Every 12 Hours		Not Reported
	Cefditoreno Pivoxilo (7358ps)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799090	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1235781		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799099	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235652		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Failure	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799108	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235526		48 YR	Female	ESP

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

Hepatitis	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;	Teva
	Hidroxicloroquina (2143a)	S			Teva
	Colchicina (142a)	S	Oral	1 U Breakfast	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Tocilizumab (8289a)	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799283	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235458		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799351	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1235378		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood	Prednisone			S	Unknown	20 Milligram Daily;		Actavis

Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Thrombosis	Prednisone	S	Unknown	20 Milligram Daily;	Actavis
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Warfarin Sodium	S	Unknown		Not Reported
	Warfarin Sodium	S	Unknown		Not Reported
	Amitriptyline	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799352	EXPEDITED (15-DAY)		OT	RO-MYLANLABS-2020M1002236		66 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Product Use In Unapproved Indication	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Mylan
	Azathioprine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799392	EXPEDITED (15-DAY)		OT	ES-BIODELIVERY SCIENCES INTERNATIONAL-2020BDSI0343		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tinnitus	Fentanyl Citrate			S	Unknown			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Ritonavir/Lopinavir			S	Oral	(5 Ml/12h)		Not Reported
	Midazolam			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	200mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799618	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1048632		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg		Mylan
	Roactemra			C				Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	2 Gr Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799624	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1048642		57 YR	Female	ESP

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

Condition Aggravated; Hepatitis	Azithromycin		S	Oral	500 Milligram, (500 Mg Dia)	Not Reported
	Lopinavir/Ritonavir		S	Oral	Unk, Bid, (2u Cada 12h)	Not Reported
	Lopinavir/Ritonavir		S			Not Reported
	Roactemra		S	Intravenous (not otherwise specified)	600 Mg	Mylan
	Roactemra		S			Mylan
	Hidroxicloroquina /00072601/		S	Oral	400 Mg Dia	Mylan
	Hidroxicloroquina /00072601/		S			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799987	EXPEDITED (15-DAY)		HO, OT	ES-ABBVIE-20K-144-3400696-00		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Shock	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801751	DIRECT	Y	LT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	Other Frequency:Bid X1day,Then Qd;		Sandoz
	Meropenem 500mg Iv			C				Not Reported
	Acetaminophen 650mg Po			C				Not Reported
	Aspirin 81mg Po			C				Not Reported
	Atorvastatin 40mg Po			C				Not Reported
	Enoxaparin 40mg Sc			C				Not Reported
	Gabapentin 300mg Po			C				Not Reported
	Hydroxychlorothiazide 25mg Po			C				Not Reported
	Levothyroxine 25 Mcg Po			C				Not Reported
	Lisinopril 40mg Po			C				Not Reported

	Sertraline 50mg	C	Not Reported
	Azithromycin 500mg Iv	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801911	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	11179339	EXPEDITED (15-DAY)		OT	CA-ROCHE-1590696		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Drug Interaction; Drug Interaction; Hepatotoxicity; Joint Swelling; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Response	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Leflunomide			S	Oral	Therapy Duration: 9 Months		Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 13 Years		Not Reported

Decreased; Thyroid Neoplasm; Thyroid Neoplasm; Toxicity To Various Agents; Toxicity To Various Agents	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12117854	EXPEDITED (15-DAY)		OT	CA-ROCHE-1630803		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Actemra			S	Unknown	Stopped		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Stopped.		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12197652	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1727368		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Infection; Inflammation; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]			C	Unknown			Not Reported
	Diphenoxylate			C	Unknown	2.5/0.025 Mg Daily		Not Reported
	Actonel			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported

Ferrous Gluconate	C	Unknown		Not Reported
Nasonex	C	Unknown	2 Sprays Intranasal	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	3-4 Times/Day.	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	1 Dosage Form	Not Reported
Ergocalciferol	C	Unknown		Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
Loperamide Hydrochloride	C	Unknown		Not Reported
Pantoprazole Magnesium	C	Unknown		Not Reported
Tylenol	C	Oral		Not Reported
Tylenol	C	Oral		Not Reported
Trazodone Hydrochloride	C	Oral		Not Reported
Perphenazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12511500	EXPEDITED (15-DAY)		OT	CA-ROCHE-1784162			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Apo-Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12919635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1851565		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment	Actemra			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

Failure	Humira	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12946333	EXPEDITED (15-DAY)		OT	CA-ROCHE-1853943		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Other	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13112057	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876559		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous	Therapy Duration: 8 Months		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Therapy Duration: 6 Months		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Meloxicam			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13210355	EXPEDITED (15-DAY)		OT	CA-SA-2015SA178527		40 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13229065	EXPEDITED (15-DAY)		OT	CA-ROCHE-1892565		46 YR	Female	CAN

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

Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	4.0 Months	Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 2.0 Year(S)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Xeljanz	S	Oral	Therapy Duration 505.0 Day(S)	Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 4.0 Month(S)	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Therapy Duration 2.0 Years	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Ketorolac	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13966976	EXPEDITED (15-DAY)		OT	CA-ROCHE-1992036			Female	CAN

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

Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Response Decreased	Actemra	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration: 245.0 Nos		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Enbrel	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	14444966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2056327		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Treatment Failure; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Arava	C	Oral	Not Reported
Risedronate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15598301	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA021997		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown	Unk Unk, Unk		Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported

Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Tocilizumab		S			Not Reported
	Etanercept		S		15 Mg Qwk	Not Reported
	Adalimumab		S	Subcutaneous	40 Mg, Qwk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	420 Mg, Unk	Not Reported
	Infliximab		S	Unknown	200 Mg, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15781203	EXPEDITED (15-DAY)		OT	CA-SA-2018SA397121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil Sulfate			C				Not Reported

Desoximetasone	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15832234	EXPEDITED (15-DAY)		DS	CA-ROCHE-1893094		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondropathy; Disability; Drug Ineffective; Headache; Malaise; Sarcoidosis; Tooth Extraction; Tooth Fracture; Weight Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported
	Cephalexin Monohydrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16226845	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA110472			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S		Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C		20 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16231995	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S			Not Reported
	Xeljanz	S			Not Reported
	Prednisone	C	Unknown	10 Mg	Not Reported
	Cimzia	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16425615	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1061416		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Teva
	Losartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16646742	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202696		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Plaquenil			S	Oral			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	Unk, Qow		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel			S	Subcutaneous	Unk, Duration: 129		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Prednisone	C	Oral	6 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Mefenamic Acid	C			Not Reported
	Dequalinium Chloride	C			Not Reported
	Tylenol [Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16650736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qw		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Prednisone			C	Oral			Not Reported
	Tofacitinib Citrate			C				Not Reported

	Leflunomide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16650744	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202752		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C		15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16651231	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202759		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Sanofi
	Leflunomide			S	Unknown	5 Mg		Sanofi
	Leflunomide			S	Oral	10 Unk		Sanofi
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Cyclical, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qcy, Cyclical		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Prednisone	C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16651242	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202767		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment	Plaquenil			S				Sanofi
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2		Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg		Not Reported
	Rituximab			S		Unk		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Orencia			S				Not Reported
	Orencia			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Qw		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qw		Not Reported
	Adalimumab			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Qw		Not Reported
	Etanercept			S		15 Mg, Qw		Not Reported
	Etanercept			S	Subcutaneous	15 Mg, Qw		Not Reported
	Abatacept			S				Not Reported

Failure; Vascular Access Complication; White Blood Cell Count Increased	Abatacept		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16651276	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	600 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw [1 Every 1 Week(S)]		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C	Unknown	1 Df, Qw [1 Every 1 Week(S)]		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous	Formulation: Solution		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd [2 Every 1 Day(S)]		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16655167	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint	Hydroxychloroquine			S	Unknown	2 Df, Bid,200 Mg		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Humira	S	Unknown	200 Mg, Biw, Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown	25 Mg, Biw	Not Reported
	Orencia	S	Unknown	Unk Unk, Unk	Not Reported
	Tocilizumab	S	Unknown	Unk Unk, Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk Unk, Unk, Solution Intramuscular	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Qm	Not Reported
	Xeljanz	S	Unknown	Unk Unk, Unk	Not Reported
	Desoximetasone	C	Unknown	Unk Unk, Unk	Not Reported
	Darifenacin Hydrobromide	C	Unknown	Unk Unk, Unk	Not Reported
	Darifenacin	C	Unknown	Unk Unk, Unk	Not Reported
	Ativan	C	Unknown	Unk Unk, Unk	Not Reported
	Codeine	C	Unknown	Unk Unk, Unk	Not Reported
	Anakinra	C	Unknown	Unk Unk, Unk	Not Reported
	Dexamethasone	C	Unknown	Unk Unk, Unk	Not Reported
	Dilaudid	C	Unknown	Unk Unk, Unk	Not Reported
	Diphenhydramine	C	Unknown	Unk Unk, Unk	Not Reported
	Furosemide	C	Unknown	Unk Unk, Unk	Not Reported
	Hydromorphone	C	Unknown	Unk Unk, Unk	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Unk Unk, Unk,Suspension Intra-Articular	Not Reported
	Loperamide	C	Unknown	Unk Unk, Unk	Not Reported
	Morphine Sulphate	C	Unknown	Unk Unk, Unk	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Unk Unk, Unk	Not Reported
	Omnaris	C	Unknown	Unk Unk, Unk, Spray Metered Dose	Not Reported
	Oxyneo	C	Unknown	Unk Unk, Unk,Tablet-Extended Release	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk Unk, Unk Tablet	Not Reported

				Enteric Coated	
	Pantoprazole Sodium Anhydrous	C	Unknown	Unk Unk, Unk	Not Reported
	Restasis	C	Unknown	Unk Unk, Unk, Emulsion	Not Reported
	Synthroid	C	Unknown	Unk Unk, Unk	Not Reported
	Trimethoprim	C	Unknown	Unk Unk, Unk	Not Reported
	Urispas	C	Unknown	Unk Unk, Unk	Not Reported
	Vagifem	C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16655179	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202618		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Folic Acid			S		Unk		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Methotrexate			S		20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Arava			S		Unk		Sanofi
	Cortisone Acetate			S		25 Mg		Not Reported

Alendronate Sodium	S		Unk	Not Reported
Sulfasalazine	S		500 Mg	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Actemra	S		Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Golimumab	S		Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Salazopyrin	C		Unk	Not Reported
Diclofenac	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16656983	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202972		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated;	Hydroxychloroquine			S	Oral	1 Df, Qd		Sanofi
	Plaquenil			S	Oral	1 Df, Qd		Sanofi

Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide	S	Oral	1 Df, Qd	Sanofi
	Leflunomide	S	Oral	1 Mg, Qd	Sanofi
	Arava	S		1 Df, Qd	Sanofi
	Mefenamic Acid	S		2 Df, Qd	Not Reported
	Mefenamic Acid	S		2 Df, Qd	Not Reported
	Mefenamic Acid	S		2 Df, Qd	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Methotrexate	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S		Unk Unk, Qw	Not Reported
	Enbrel	S		1 Df	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Xeljanz	S	Oral	2 Df, Qd (5 Mg Stength)	Not Reported
	Xeljanz	S		Unk	Not Reported
	Xeljanz	S		2 Df, Qd	Not Reported
	Xeljanz	S		2 Df, Qd (5 Mg Stength)	Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16686491	EXPEDITED (15-DAY)		OT	CA-SA-2019SA209083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling;	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	600 Mg, Qw		Sanofi

Rheumatoid Arthritis	Hydroxychloroquine		S	Oral	20 Mg, Qd	Sanofi
	Methotrexate		S	Oral	10 Mg, Qw	Not Reported
	Actemra		S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk Unk, Unk	Not Reported
	Folic Acid		C	Unknown	1 Df, Qw	Not Reported
	Prednisone		C	Unknown	Unk Unk, Unk	Not Reported
	Simponi		C	Unknown	Unk Unk, Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Xeljanz		C	Oral	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16710769	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2019SF17234			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Ramipril			S	Oral			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Oral			Not Reported
	Volibris			S	Oral			Not Reported
	Eliquis			S	Unknown			Not Reported
	Eliquis			S	Unknown			Not Reported
	Quensyl			S	Unknown			Not Reported

	Quensyl	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Sildenafil Citrate	S	Unknown	Not Reported
	Roactemra	S	Subcutaneous	Not Reported
	Roactemra	S	Subcutaneous	Not Reported
	Spasmolyt	S	Unknown	Not Reported
	Spasmolyt	S	Unknown	Not Reported
	Spasmolyt	S	Unknown	Not Reported
	Spasmolyt	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16939747	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436179		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Ciclosporin	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17132363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489219			Female	CAN

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

	Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17134891	EXPEDITED (15-DAY)		LT	CA-ROCHE-2485918		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S	Unknown	Not Reported
Marijuana	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S		Not Reported
Oxycodone	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Xeljanz	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S		Not Reported
Cannabis Sativa	S	Unknown	Not Reported
Kineret	C	Unknown	Not Reported

	Lyrica			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17154597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456781		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17250077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Off Label Use; Oral	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported

Discomfort; Rheumatoid Arthritis; Treatment Failure	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17265226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516327		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Etanercept	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methylprednisolone	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17310198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528070		47 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17391683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17654444	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017303		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Plaquenil			S	Unknown	3 Dosage Form		Not Reported
	Plaquenil			S	Unknown	2 Dosage Form, Two Times A Day (One In Morning And One In Evening)		Not Reported

Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Plaquenil	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17668617	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002364			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Off Label Use; Pneumonia Bacterial; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600mg In The Morning, 400mg In The Evening Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 Ml, Bid (Q12h)		Not Reported
	Lovenox			S	Subcutaneous	0.7 Ml, Qd		Not Reported
	Lovenox			S	Subcutaneous	1.4 Ml, Qd		Not Reported
	Paracetamol			S		4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Lasilix			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Tienam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17673548	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017887		74 YR	Male	FRA

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

Death	Levofloxacine Arrow Film-Coated Tablets 500mg	S	Oral	2 Dosage Form, Once A Day	Aurobindo
	Sandoz Amoxi Clav	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Lovenox	S	Subcutaneous	1 Dosage Form, Once A Day	Not Reported
	Primperan	S	Oral	1 Dosage Form	Not Reported
	Ritonavir Mylan	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Azithromycine Sandoz [Azithromycin]	S	Oral	4 Dosage Form, Once A Day	Not Reported
	Doliprane	S	Oral	1 Dosage Form	Not Reported
	Plaquenil	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Darunavir Mylan	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17678836	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017962		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	1000 Milligram, Once A Day		Aurobindo
	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17730463	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589860			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17732452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590075		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported

Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Product Use In Unapproved Indication; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	190.0 Days	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Estrogel	C	Unknown		Not Reported
	Estrogel	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Zingiber Officinale	C	Oral		Not Reported

	Acetaminophen	C	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17751944	EXPEDITED (15-DAY)		OT	CA-ROCHE-1710933		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17752813	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045214		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported

	Dolquine	S	Other	400 Mg Dia		Mylan
	Dolquine	S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17752858	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1045229		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Drug Interaction; Off Label Use; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17754839	EXPEDITED (15-DAY)		OT	CA-ROCHE-1674787		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Singleuse, Preservativefree Prefilled Syringes		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 107 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Azathioprine	S	Intravenous (not otherwise specified)	Not Reported
Azathioprine	S	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Anakinra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17757977	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200500983			Female	CAN

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

Abdominal Discomfort; Abscess; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatic Fibrosis; Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis; Sepsis; Spinal Cord Infection	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S		Not Reported
	Azathioprine	S		Not Reported
	Diclofenac	S		Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Mobicox	S		Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Naproxen	S		Not Reported
	Sulfasalazine	S		Not Reported
	Vioxx	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Intramuscular	Not Reported
	Plaquenil /00072602/	C		Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17757980	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500974		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Crohn'S Disease; Drug Ineffective; Elbow Operation; Inappropriate Schedule Of Product Administration; Neck Pain; Off Label Use; Pain In Extremity; Product Dose Omission; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17758008	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500964		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17758010	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Bupropion	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17764530	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596720		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17765745	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17771016	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1045647		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use;	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

Sinus Bradycardia	Plaquenil /00072603/	S	Oral	600 Milligram, Qd	Mylan
	Zithromax	S	Oral	500 Milligram, Qd	Mylan
	Zyvoxid	C	Intravenous (not otherwise specified)	1200 Milligram	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17800342	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005269			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597847			Female	CAN

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

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801162	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122504			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Pethidine Hydrochloride			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Sanofi
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Mg		Sanofi
	Levofloxacin			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arthrotec			S	Intracardiac			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Lyrica			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801165	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247402		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia ()		Sun
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Lopinavir/Ritonavir			S	Oral	2u Cada 12h ()		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801207	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201806-001951			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Fatigue; Gait Disturbance	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801367	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005477			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602160			Female	CAN

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

Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Bupropion	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	Tablet (Extendedrelease)	Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801454	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005382			Unknown	USA

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

Death; Product Use In Unapproved Indication	Hydroxychloroquine	S	Unk	Concordia
	Azithromycin	S	Unk	Not Reported
	Sirolimus	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801559	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598903		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Sulfate]				
Prednisone		S	Unknown	Not Reported
Prednisone		S	Unknown	Not Reported
Remicade		S	Intravenous (not otherwise specified)	Not Reported
Rituxan		S	Intravenous drip	Not Reported
Simponi		S	Subcutaneous	Not Reported
Sulfasalazine		S	Unknown	Not Reported
Sulfasalazine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801662	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202968		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Eye Disorder; Joint Swelling; Mobility Decreased; Musculoskeletal Pain; Ocular Toxicity; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	400mg, Qd: 1 Every 1 Day (S)		Sanofi
	Leflunomide			S	Unknown	20mg, Qd: 1 Every 1 Days (S)		Sanofi
	Methotrexate			S	Oral	20mg, Qw: 1 Every 1 Week(S)		Not Reported
	Arava			S	Unknown			Sanofi
	Orencia			S	Unknown	125mg, Qw: 1 Every 1 Week(S)		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw; 1 Every 1 Week(S)		Not Reported
	Humira			S	Subcutaneous	40mg, Qow : 1 Every 2 Week(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801713	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598629			Female	CAN

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

Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Leflunomide	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802035	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3408590-00		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Pain	Kaletra 200/50			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Omeprazol			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802249	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802251	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802291	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020020250		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cardiac Disorder; Contusion; Croup Infectious; Drug Ineffective; Fatigue; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased; Hypersensitivity; Hypertension; Hypotension; Immunosuppression;	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Monthly (Qm)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, Monthly (Qm)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S		20 Milligram, Weekly (Qw)		Not Reported
	Rosuvastatin Calcium			S				Not Reported
	Sulfasalazine			S				Not Reported
	Folic Acid			C				Not Reported
	Humalog			C				Not Reported
	Sertraline Hydrochloride			C				Not Reported
	Synthroid			C				Not Reported

Influenza; Infusion Related Reaction; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pain; Pain In Extremity; Pertussis; Productive Cough; Rash; Stress; Therapeutic Response Decreased; Treatment Failure; Weight Decreased; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe.		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802457	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236226			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazol	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802571	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600294			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Cortisone Acetate	C	Subcutaneous		Not Reported
Desoximetasone	C	Oral		Not Reported
Diclofenac	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802668	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802709	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235783		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Vessel	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Mg		Not Reported

Puncture Site Haemorrhage	Dexametasona (722a)	S	Intravenous (not otherwise specified)	20 Milligram Daily;	Not Reported
	Acetilsalicilato De Lisina	S	Intravenous (not otherwise specified)	200 Mg	Not Reported
	Adiro 100 Mg Comprimidos Gastrorresistentes Efg , 500 Comprimidos	S	Oral	100 Milligram Daily; Cp	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601899		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802778	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236801		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Prednisolone			S	Unknown			Actavis
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported

Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Celebrex		S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Cyclobenzaprine		C	Unknown		Not Reported
	Desoximetasone		C	Unknown	5 Milligram Daily;	Not Reported
	Desoximetasone		C	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Prednisone Acetate		C	Unknown	5 Milligram Daily;	Not Reported
	Tylenol/00020001/		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802781	EXPEDITED (15-DAY)		HO	ES-ACCORD-182405		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600492		42 YR	Female	CAN

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

Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Enbrel	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	3.0 Years		Not Reported
	Sulfasalazine	S	Unknown	3.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802794	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-182375		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802827	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597599		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoporotic Fracture; Spinal Compression Fracture	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C	Unknown	Tablet (Extended Release)		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802925	EXPEDITED (15-DAY)		OT	CA-ROCHE-1956506		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Nodule; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802931	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600444		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Kevzara	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802958	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802965	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803035	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005562			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803036	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005560			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803037	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005561			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803109	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-182473		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Colchicine			S	Oral	0.5 Mg Every 12 H		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803135	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236219		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803232	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503708		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Otezla			S	Oral			Celgene
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Dosage Forms		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803307	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005559			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803317	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235961		56 YR	Male	ESP

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

Atrioventricular Block First Degree	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;		Teva
	Hidrocortisona (54a)	S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803365	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598528		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Synovitis; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803486	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045225		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803597	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005393			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported
	Prednisone			C		High Dose		Not Reported
	Levofloxacin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803605	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-16827		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Brenzys			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Oral	15 To 20 Mg (More Than Three Months)		Not Reported
	Hydroxychloroquine			S	Unknown	200 To 400 Mg (More Than Three Months)		Not Reported

	Orencia			S	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803681	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2595853		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803729	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803809	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1048495		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium /01479302/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Lovenox			S	Subcutaneous	Unk		Mylan
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Loxen /00639802/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Sufentanil			C		Unk		Mylan
	Nimbex /01302502/			C		Unk		Mylan
	Hypnovel /00634101/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598105		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235944			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)		
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Tofacitinib Citrate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598433		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235976			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Calcium Carbonate			S	Oral	3 Dosage Forms Daily;		Not Reported
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Relafen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported
	Magnesium Aspartate			C	Oral	3 Dosage Forms Daily;		Not Reported

	Omega 3 [Fish Oil]			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804016	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate			S	Unknown			Barr
	Mycophenolate Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804088	EXPEDITED (15-DAY)		HO	ES-GLAXOSMITHKLINE-ES2020079133		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Glaxosmithkline
	Symbicort Turbuhaler			S	Respiratory (inhalation)	2-2-2		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804295	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598537		61 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804335	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1048553		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd, 500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd, 2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Milligram, Qd, 400 Mg Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804502	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200503932		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell	Otezla			S	Oral			Celgene
	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S				Celgene
	Actemra			S	Unknown	680 Milligram		Not Reported

Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Actemra	S	Unknown	360 Milligram	Not Reported
	Actemra	S	Unknown	2.68 Milligram	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Ibuprofen	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	380 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Cyclosporin	S	Unknown		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Infliximab	S	Oral		Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Oral	12 Milligram	Not Reported

Methotrexate	S	Oral	10 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Oral	10 Milligram	Not Reported
Methotrexate	S	Oral	10 Milligram	Not Reported
Methotrexate	S	Oral	10 Milligram	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram	Not Reported
Methotrexate	S	Unknown	17.5 Milligram	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
Mogadon	S	Oral	5 Milligram	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Myochrysine	S	Intramuscular	25 Milligram	Not Reported
Orencia	S	Intravenous drip	760 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram	Not Reported
Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous drip		Not Reported
Rituxan	S	Unknown	2000 Milligram	Not Reported
Rituximab	S	Intravenous drip	2000 Milligram	Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Diphenhydramine Hcl	C	Unknown		Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C	Oral		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Nitrazepam	C	Unknown	5 Milligram	Not Reported
	Oxycodone	C	Unknown		Not Reported
	Prednisolone	C	Unknown	20 Milligram	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported
	Prednisolone	C	Unknown	20 Milligram	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported
	Uloric	C	Unknown	160 Milligram	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804544	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-014075		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree	Hidrocortisona			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804908	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020196604		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Tercian [Cyamemazine Tartrate]			S	Oral	25 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day (Every 12h)		Not Reported
	Paroxetine			C	Oral	30 Mg, Daily		Not Reported
	Depakine [Valproic Acid]			C	Oral	1000 Mg, Daily		Not Reported
	Aerius [Desloratadine]			C	Oral	5 Mg, Daily		Not Reported
	Xanax			C	Oral	0.75 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805526	EXPEDITED (15-DAY)		HO	US-AMNEAL PHARMACEUTICALS-2020-AMRX-01419		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Daily		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805668	EXPEDITED (15-DAY)		HO	ES-ACCORD-182362		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Doxycycline			S	Oral	100 Mg Every 12 Hours		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805673	EXPEDITED (15-DAY)		HO	ES-ACCORD-182373		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral			Not Reported
	Ivermectin			S	Oral	12 Mg Du		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Hydroxychloroquine			S	Oral	800 Mg Day (Loading) Followed By 400 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17811689	DIRECT	N	HO			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil Tab 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	18266292	DIRECT					6 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Azithromycin			S	Oral		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	14351652	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268415		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Grip Strength Decreased; Rheumatoid	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi

Arthritis	Prednisone	S	Unknown	20 Mg,Unk	Not Reported
	Prednisone	S	Unknown	40 Mg,Qd	Not Reported
	Sulfasalazine	S	Oral	2 Mg, Qd	Not Reported
	Enbrel	S	Unknown	Unk Unk,Qw	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, 1 Every 1 Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	14875538	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126619			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Qd		Sanofi
	Arava			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Qw		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15193064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15275893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C	Unknown			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C				Not Reported
	Adalimumab			C				Not Reported

	Bcg	C	Not Reported
	Clavulanate Potassium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15390537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185424			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15705892	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181205173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment;	Levaquin			S	Unknown			Not Reported
	Avelox			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Keflex			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Losartan			S	Unknown			Not Reported
	Hydralazine Hydrochloride			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cephalexin Monohydrate			S	Unknown			Not Reported

Malaise; Multiple Allergies; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Cephalexin	S	Unknown	Not Reported
	Enalapril	S	Unknown	Not Reported
	Enalapril Maleate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hctz	S	Unknown	Not Reported
	Hydrochlorothiazide	S	Unknown	Not Reported
	Isoniazid	S	Unknown	Not Reported
	Losartan Potassium	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Metoprolol Tartrate	S	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Pariet	S	Unknown	Not Reported
	Penicillin G /00000902/	S	Unknown	Not Reported
	Penicillin G /00000903/	S	Unknown	Not Reported
	Plaquenil S	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Not Reported
	Tecta	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Venofer	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Atenolol	C	Unknown	Not Reported
	Colchicine	C	Unknown	Not Reported
	Coversyl	C	Unknown	Not Reported

	Leucovorin	C	Unknown		Not Reported
	Levothyroxine Sodium	C	Unknown		Not Reported
	Ranitidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	16823349	EXPEDITED (15-DAY)		OT	CA-SAKK-2019SA185374AA		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Sarilumab			S				Sanofi
	Cortisone Acetate			S				Not Reported
	Desoximetasone			S				Sanofi
	Diclofenac Sodium			S				Not Reported
	Topicort			S	Cutaneous			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S		Unk		Not Reported
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Desoximetasone			S	Oral			Sanofi
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S		1 Df, Qd		Sanofi
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Paracetamol			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Sanofi

Folic Acid	S				Not Reported
Stelara	S				Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Methotrexate Sodium	S	Oral			Not Reported
Golimumab	S				Not Reported
Cimzia	S	Subcutaneous	Unk, Qd		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S				Not Reported
Hydroxychloroquine	S		Unk		Not Reported
Hydroxychloroquine	S	Oral	1 Df, Qd		Not Reported
Actemra	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Atasol [Paracetamol]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	16849610	EXPEDITED (15-DAY)		OT	CA-ROCHE-2411011		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenou	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17250742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514001		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17299256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524986		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz Xr	C		Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17333671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530860		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Infliximab	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17358367	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530347		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Nortriptyline	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Nasonex	C	Unknown	Not Reported
	Aclasta	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Ascorbic Acid	C		Not Reported
	Biotin	C		Not Reported
	Calcium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C		Not Reported
	Fentanyl	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Loperamide	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
	Omega 3-6-9 [Fish Oil]	C	Unknown	Not Reported

	Oxycodone Terephthalate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Pyridoxine	C		Not Reported
	Sodium	C		Not Reported
	Thiamine Hcl	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin A [Retinol]	C		Not Reported
	Vitamin B3	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17696997	EXPEDITED (15-DAY)		HO, OT	BE-ADVANZ PHARMA-202004003502			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	400 Mg, Bid, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Film-Coated Tablet		Concordia
	Haldol			C		Unk		Not Reported
	Paracetamol			C		1 Unk		Not Reported
	Fraxiparine			C		Unk		Not Reported
	Dafalgan Forte			C		1 G		Not Reported
	Morphine			C		10 Mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17701011	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244837		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Ranbaxy
	Azithromycin			S	Oral	500 Milligram, Daily		Sun

	Hidroxicloroquina Sulfato (2143su)	S	Oral	200 Milligram, Daily	Not Reported
	Hidroxicloroquina Sulfato (2143su)	S			Not Reported
	Lopinavir+Ritonavir	S	Oral	2 Dosage Form, Bid	Not Reported
	Tacrolimus (2694a)	S	Oral	Unk	Not Reported
	Enoxaparina Sodica (2482so)	C	Subcutaneous	40 Milligram, Daily	Not Reported
	Prednisona (886a)	C	Oral	20 Milligram, Daily	Not Reported
	Ceftriaxona (501a)	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17750410	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1230308		26 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Suicide Attempt	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Alopurinol 100 Mg Comprimido			C	Oral	100 Mg		Not Reported
	Paracetamol (12a)			C	Oral	1 Gram 8 Hours		Not Reported
	Famotidina 20 Mg Comprimido			C	Oral	20 Mg		Not Reported
	Doxazosina (2387a)			C	Oral	4 Mg		Not Reported
	Ceftriaxona 2.000 Mg Inyectable Iv			C	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Cefixima (2400a)			C	Oral	200 Mg 12 Hours		Not Reported
	Magnogene 53 Mg Comprimidos Recubiertos			C	Oral	106 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Prednisona (886a)			C		5 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Carvedilol 25 Mg Comprimido			C	Oral	25 Mg		Not Reported
	Zemplar 1 Microgramo Capsulas Blandas			C	Oral	1 Microgram		Not Reported
	Myfortic 360 Mg Comprimidos Gastrorresistentes			C	Oral	360mg 12 Hours		Not Reported
	Enoxaparina Sodio 20 Mg (2.000			C	Subcutaneous	20 Mg		Not Reported

Ui) Inyectable 0,2 Ml Fosrenol	C	Oral	750 Mg 12 Hours		Not Reported
Metamizol 575 Mg Capsula	C	Oral	575 Mg		Not Reported
Tacrolimus (2694a)	C	Oral	2 Mg		Not Reported
Tacrolimus (2694a)	C	Oral	2 Mg		Not Reported
Tacrolimus (2694a)	C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17767549	EXPEDITED (15-DAY)		HO	FI-BAUSCH-BL-2020-013895			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pneumonia Streptococcal	Prednisolone			S	Unknown	2 Subjects; Combination With Mtx, And Bdmard; Combination With Mtx, And Certolizumab (Third Bdmard)		Not Reported
	Prednisolone			S	Unknown	One Subject; Combination With Leflunomide, And Hydroxychloroquine		Not Reported
	Methotrexate			S	Unknown	Two Subjects		Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown	One Subject		Not Reported
	Hydroxychloroquine			S	Unknown	One Subject		Not Reported
	Certolizumab			S	Unknown	Third Bdmard; One Subject		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17804897	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1236797		24 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva

	Lopinavir/Ritonavir Sandoz 200 Mg/50 Mg Comprimidos Recubiertos Con Pe	S	Oral	4 Dosage Forms Daily; 200 Mg / 50 Mg	Not Reported
	Interferon Beta-1b (2305od)	S	Subcutaneous	0.25 Mg	Not Reported
	Cloroquina [Chloroquine]	S	Oral	310 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805222	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598386		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported

Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Cymbalta	C		Not Reported
	Hydromorphone	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805262	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2062		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fall; Gait Inability; Malaise; Paralysis; Spinal Fracture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805480	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598565		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Risedronic Acid	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805708	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004352			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Dupixent			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601279			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805795	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247183		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Sun
	Hydroxychloroquine			S	Unknown	1200 Milligram		Sun
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805896	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805934	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598728		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806026	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3408720-00		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Septic Shock	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598842		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Insulin			C	Oral			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported

	Metformin	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Ramipril	C		Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806054	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806078	EXPEDITED (15-DAY)		HO	ES-ACCORD-182452		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Enoxaparin			S	Subcutaneous	60 Mg Cada 12 Horas		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg Daily For 6 Days Followed By 10 Mg Daily X 5 Days		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598032		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806227	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236784			Female	CAN

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

Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulphathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806262	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-014818			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Bausch And Lomb
	Erythromycin			S	Unknown			Bausch And Lomb
	Demerol			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Bisoprolol	S	Unknown	Not Reported
	Erythromycin Base	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Norfloxacin	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Arthrotec	S	Unknown	Not Reported
	Arthrotec	S		Not Reported
	Ceclor	S	Unknown	Not Reported
	Celebrex	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Unknown	Not Reported
	Meperidine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806334	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598098		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness;	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ergocalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806352	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598841		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806362	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005325			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Zpac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806482	EXPEDITED (15-DAY)		OT	ES-ACCORD-182526		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Sulpiride			S	Oral	50 Mg Every 8 Hours		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806634	EXPEDITED (15-DAY)		HO	ES-ACCORD-182639		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Off Label Use; Vessel Puncture Site Haemorrhage	Hydroxychloroquine			S	Oral	400 Mg		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg Dia		Not Reported

	Lysine Acetylsalicylate		S	Intravenous (not otherwise specified)	200 Mg	Not Reported
	Adiro		S	Oral	1 Cp Day, 100 Mg Gastro-Resistant Tablets Efg, 500 Tablets	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806646	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1237680		67 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Rash Pruritic	Levofloxacino (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806764	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599986			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599020		64 YR	Female	CAN

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

	Desoximetasone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone Acetate	C	Unknown		Not Reported
	Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807174	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598813		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807176	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gait Disturbance; Myocardial Infarction; Pain; Swelling; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Codeine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807183	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598569		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598518			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Intentional Product Use Issue; Off Label Use; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807193	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247372		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam		C		Not Reported
	Sulfasalazine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807237	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported

Darifenacin Hydrobromide	C		Not Reported
Desoximetasone	C		Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C		Not Reported
Morphine Sulfate	C		Not Reported
Vagifem	C		Not Reported
Urispas	C		Not Reported
Trimethoprim	C		Not Reported
Synthroid	C		Not Reported
Omnaris	C		Not Reported
Oxyneo	C		Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Restasis	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598520		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C		Not Reported
	Ativan	C		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Codeine	C		Not Reported
	Darifenacin	C		Not Reported
	Darifenacin Hydrobromide	C		Not Reported
	Desoximetasone	C		Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Pantoprazole	C		Not Reported
	Restasis	C		Not Reported
	Rituximab	C	Intravenous drip	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C		Not Reported
	Vagifem	C		Not Reported
	Kadian	C		Not Reported
	Kenalog [Triamcinolone Acetonide]	C		Not Reported
	Lasix [Furosemide]	C		Not Reported
	Loperamide	C		Not Reported
	Morphine Sulfate	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807267	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2020-FR-1237207		81 YR	Male	FRA

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

Electrocardiogram Qt Prolonged; Ventricular Extrasystoles	Nebivolol	S	Oral	5 Mg		Actavis
	Plaquenil	S	Oral	600 Mg		Not Reported
	Valsartan	C	Oral	160 Mg		Not Reported
	Augmentin	C	Oral	3 Gm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597899		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807382	EXPEDITED (15-DAY)		HO	ES-ACCORD-182384		71 YR	Male	ESP

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

Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine		S	Oral	400 Mg Day	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Azithromycin		S	Oral	500 Mg Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598837		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Actemra			S	Subcutaneous			Not Reported

Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Adalimumab		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807451	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019154		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; Diarrhoea; Drug Ineffective; Joint Swelling; Migraine; No Adverse Event; Peripheral Swelling; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown	7 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Rituxan	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Prednisone	S	Unknown	7 Milligram Daily;	Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral	10 Milligram Daily;	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram Daily;	Not Reported
Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram Daily;	Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Cipralex [Escitalopram]	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Hydromorphone Hcl	C	Oral	6 Milligram Daily;	Not Reported
Mupirocin	C	Topical		Not Reported
Mupirocin	C	Topical		Not Reported

	Pantoloc [Pantoprazole]	C			Not Reported
	Tapentadol Hydrochloride	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported
	Tramacet	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807497	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598405		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Butterfly Rash; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807531	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598745		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807727	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503765			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Otezla			S	Unknown			Celgene
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Infliximab	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Advair	C	Unknown	Not Reported
Allopurinol	C	Unknown	Not Reported
Atrovent Hfa	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Cyclobenzaprine Hydrochloride	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Esomeprazole Magnesium Hydrate	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Leucovorin Calcium	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Ventolin Hfa	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807730	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597720		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Zingiber Officinale			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807840	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK202004826		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Midazolam (Manufacturer Unknown)			S	Unknown	Unk		Fresenius Medical Care
	Ceftriaxon (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg/12 H		Not Reported

	Ritonavir/Lopinavir	S	Oral	5 Ml/ 12 H (80 Mg + 20 Mg) / Ml Oral Solution, 5 Bottles Of 60 Ml + 5 Syringes Of 5 Ml)		Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807894	EXPEDITED (15-DAY)		OT	ES-ACCORD-182460		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807895	EXPEDITED (15-DAY)		HO	ES-ACCORD-182670		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Symbicort Turbuhaler			S	Respiratory (inhalation)	2-2-2, 160 Micrograms / 4.5 Micrograms / Inhalation Powder For Inhalation, 1 Inhaler Of 120 Doses		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807925	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2601473		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sodium Aurothiomalate			S				Not Reported

Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S				Not Reported
Xeljanz	S	Oral			Not Reported
Minocycline Hydrochloride	S	Unknown			Not Reported
Cannabis Sativa	S	Unknown			Not Reported
Ilaris	S	Subcutaneous	Single-Use Vial		Not Reported
Oxycodone	S	Unknown			Not Reported
Gold	S	Unknown			Not Reported
Rituximab	C	Unknown			Not Reported
Lyrica	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807960	EXPEDITED (15-DAY)		OT	DK-PFIZER INC-2020197070		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Feet Syndrome; Dry Mouth; Intervertebral Disc Protrusion; Neuropathy Peripheral; Osteopenia; Pain In Extremity; Small Fibre Neuropathy	Methotrexate			S		15 Mg, Weekly		Pfizer
	Methotrexate			S		20 Mg, Weekly		Pfizer
	Methotrexate			S		25 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Prednisolone			C	Oral	12.5 Mg, Daily		Not Reported
	Prednisolone			C	Oral	Dose Reduced		Not Reported
	Prednisolone			C	Oral	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808058	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC-2020198873		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia;	Meropenem			S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)		Pfizer
	Linezolid			S	Intravenous (not	600 Mg, 2x/Day (Every 12		Pfizer

Upper Gastrointestinal Haemorrhage			otherwise specified)	Hours)		
	Roactemra	S		600 Mg, Single		Not Reported
	Roactemra	S				Not Reported
	Piperacillin/Tazobactam	S	Intravenous (not otherwise specified)	1 Df, 3x/Day (Every 8 Hours)		Not Reported
	Metamizole	S	Intravenous (not otherwise specified)	2 G, 3x/Day (2 G Every 8 Hours)		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808183	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598082		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Topicort [Desoximetasone]			S	Oral			Not Reported
	Topicort [Desoximetasone]			S	Cutaneous			Not Reported
	Topicort [Desoximetasone]			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Oral	11.0 Years	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	365.0	Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808302	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598106			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 577		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 577		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 577		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	Therapy Duration: 577		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577		Not Reported
	Orencia			S	Unknown	Therapy Duration: 577		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 577		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 577	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 577	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599535		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808362	EXPEDITED (15-DAY)		OT	NVSC2020IL137300		43 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Product Use In Unapproved Indication; Retinal Injury	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	3 Mg/Kg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808452	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil[Hydroxychloroquine Phosphate]]	S		400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808608	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020198882		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, 1x/Day		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Mg, 3x/Day (Every 8 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808668	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000390			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatocellular Injury; Off Label Use	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus

	Plaquenil /00072603/	S	Oral	Unk		Not Reported
	Plaquenil /00072603/	S				Not Reported
	Rovamycine /00074401/	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Paracetamol	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Linezolide Kabi	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Movicolon	C		Unk		Not Reported
	Amikacine /00391002/	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808728	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000391			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Off Label Use; Purpura; Thrombocytopenia	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Esomeprazole Magnesium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Noradrenaline /00127501/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Loxen /00639802/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Nimbex /01302502/			C		Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Hypnovel /00634103/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808802	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808803	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236789		59 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate	S	Unknown	20 Milligram Daily;	Barr
	Methotrexate	S			Barr
	Prednisone	S	Unknown		Actavis
	Alendronate Sodium	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported

	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17809219	EXPEDITED (15-DAY)		OT	CA-SA-2018SA288283		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Sanofi
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			C	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Cimzia			C				Not Reported
	Humira			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Arthrotec			C	Unknown			Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported
	Rabeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17809246	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058842		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Injury; Swelling	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810378	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3409473-00			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Anosmia; Blindness; Blood Lactate Dehydrogenase Abnormal; Diarrhoea; Fatigue; Gamma-Glutamyltransferase Abnormal; Hypoacusis; Malaise; Nervousness; Off Label Use	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811001	DIRECT	Y	HO			53 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	18267605	DIRECT		OT			40 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Darunavir-Cobicstat			S				Not Reported

	Interferon Beta-1b		S		4 DAY	Not Reported
	Hydroxychloroquine		S		5 DAY	Not Reported
	Azithromycin		S		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	18267610	DIRECT		DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodynamic Instability; Off Label Use; Organ Failure	Azithromycin			S	Oral			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral		7 DAY	Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	18267661	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lopinavir-Ritonavir			S			14 DAY	Not Reported
	Hydroxychloroquine			S			5 DAY	Not Reported
	Azithromycin			S			5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	18267666	DIRECT		OT			21 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumothorax	Hydroxychloroquine			S			5 DAY	Not Reported
	Azithromycin			S			5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	18267819	DIRECT	N					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Lopinavir-Ritonavir			S			3 DAY	Not Reported
	Hydroxychloroquine			S			5 DAY	Not Reported
	Azithromycin			S			5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	18271954	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue	Lopinavir-Ritonavir			S			15 DAY	Not Reported
	Hydroxychloroquine			S	Oral		15 DAY	Not Reported
	Eculizumab			S		Other Frequency:2 Doses;		Not Reported
	Ceftriaxone			S		Other Route:Iv	15 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	11631404	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1643958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Losec [Omeprazole]	C		Not Reported
	Citalopram Hydrobromide	C		Not Reported
	Crestor	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Rosuvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	12909635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1564010		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Skin Reaction; Skin Swelling; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	12974904	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1859498		48 YR	Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	13100775	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Treatment Failure; Weight Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	08/--/2002 To 05/--/2005		Not Reported
	Enbrel			S	Unknown	Duration 730 Days		Not Reported
	Arava			S	Oral	Dose And Frequency Unknown.		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown	Dose And Frequency Unknown.	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Imuran [Azathioprine]	S	Unknown	Dose And Frequency Unknown	Not Reported
Sulfasalazine	S	Unknown	Dose And Frequency Unknown.	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Ciclosporin	S	Oral	Dose And Frequency Unknown.	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Dose And Frequency Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Dose And Frequency Unknown.	Not Reported

	Cyclosporine	S	Oral	Dose And Frequency Unknown	Not Reported
	Cyclosporine	S	Unknown		Not Reported
	Cyclosporine	S	Oral		Not Reported
	Cyclosporine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown	Dose And Frequency Unknown.	Not Reported
	Azathioprine	S	Unknown	Dose And Frequency Unknown.	Not Reported
	Lyrica	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Prednisone	C			Not Reported
	Piroxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	13166185	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886967		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	14287715	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2035078		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Altace			S	Unknown	1 Unit Not Reported		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	14831436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112282		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Meloxicam	C	Oral	Not Reported
	Prednisolone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	15674323	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2018US050584			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Premature Baby	Tacrolimus			S	Transplacental	Unk, Unknown Freq.		Astellas
	Hydroxychloroquine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16318010	EXPEDITED (15-DAY)		HO	EC-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-207974		14 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Reversible Encephalopathy Syndrome	Atorvastatin			S	Unknown	10 Milligram		Sun
	Atorvastatin			S				Sun
	Enalapril			S	Unknown	5 Milligram		Ranbaxy
	Enalapril			S				Ranbaxy
	Furosemide			S	Unknown	40 Milligram		Sun
	Furosemide			S				Sun
	Hydroxychloroquine			S	Unknown	200 Milligram		Ipca
	Hydroxychloroquine			S				Ipca
	Prednisone			S	Unknown	30 Milligram		Mutual
	Prednisone			S				Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16646741	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S		200 Mg, Biw		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Tiw		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qow		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16770849	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1100415			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Actavis
	Omeprazole			S	Oral	40 Milligram Daily; 20 Mg, Bid		Actavis
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Actavis
	Ramipril			S		5 Milligram Daily;		Actavis
	Sildenafil Citrate			S	Unknown	60 Milligram Daily;		Actavis
	Volibris			S	Oral	30 Milligram Daily;		Not Reported
	Volibris			S	Oral	1 Dosage Forms Daily;		Not Reported

Roactemra	S	Subcutaneous	162 Mg, Qwk		Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Qwk		Not Reported
Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day		Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv		Not Reported
Spasmolyt	S	Unknown	15 Milligram Daily;		Not Reported
Spasmolyt	S	Unknown	30 Milligram Daily;		Not Reported
Quensyl	S	Unknown	80 Milligram Daily; 40 Mg, Bid		Not Reported
Quensyl	S	Unknown	40 Milligram Daily; 20 Mg, Bid		Not Reported
Ambrisentan	S	Oral	1 Dosage Forms Daily;		Not Reported
Ambrisentan	S	Unknown	30 Milligram Daily;		Not Reported
Lyrica	S	Unknown	100 Milligram, Tid		Not Reported
Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1)		Not Reported
Apixaban	S	Unknown	10 Milligram Daily; 2.5 Milligram, Bid		Not Reported
Apixaban	S	Unknown	2 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16906561	EXPEDITED (15-DAY)		HO	CA-ROCHE-2425931		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra;	Rituxan			S	Intravenous drip			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Off Label Use; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Erythromycin	C		Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17012579	EXPEDITED (15-DAY)		DS	CA-ROCHE-2458308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Tocilizumab	S	Unknown		Not Reported
	Imuran [Azathioprine]	C	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17386806	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200111049		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S				Celgene
	Otezla			S				Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram		Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	.1096 Milligram		Not Reported
	Methotrexate			S	Unknown	.1315 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported

Methotrexate	S	Unknown	15 Milligram		Not Reported
Methotrexate	S	Unknown	70 Milligram		Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Unknown			Not Reported
Tocilizumab	S	Unknown	360 Milligram		Not Reported
Tocilizumab	S	Unknown	680 Milligram		Not Reported
Sulfasalazine	S	Endocervical			Not Reported
Stelara	S	Subcutaneous			Not Reported
Simponi	S	Subcutaneous			Not Reported
Rituxan	S	Intravenous drip	2000 Milligram		Not Reported
Remicade	S	Intravenous drip			Not Reported
Benadryl	S	Unknown			Not Reported
Mogadon	C	Oral	5 Milligram		Not Reported
Colchicine	C	Unknown			Not Reported
Nitrazepam	C	Oral	5 Milligram		Not Reported
Dexilant	C	Oral			Not Reported
Febuxostat	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Gravol	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Uloric	C	Oral	160 Milligram		Not Reported
Oxycodone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17395477	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542443		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone	Actemra			S	Unknown			Not Reported

Disorder; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Off Label Use; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Penicillin G Sodium	S	Unknown	Not Reported
	Penicillin V Potassium	S	Unknown	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17460784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554332			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure			otherwise specified)			
	Arava	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Azathioprine Sodium	S	Unknown			Not Reported
	Imuran [Azathioprine]	S	Unknown			Not Reported
	Neoral	S	Unknown			Not Reported
	Citalopram Hydrobromide	C	Unknown			Not Reported
	Citalopram Hydrobromide	C	Unknown			Not Reported
	Citalopram Hydrobromide	C	Unknown	1.0 Dosage Forms		Not Reported
	Prednisone	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17570483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570439		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17605656	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332784		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; No Adverse Event; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Neoral	S	Oral		Not Reported
Neoral	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Rituxan	S	Endocervical		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	C	Oral	And Xeljanz Xr (Prolonged Release)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17702479	EXPEDITED (15-DAY)		OT	AU-ABBVIE-20K-008-3373197-00			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia;	Humira			S	Subcutaneous			Not Reported

Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Oxycontin	S	Unknown	Not Reported
	Sildenafil	S	Oral	Not Reported
	Glyceryl Trinitrate	S	Oral	Not Reported
	Prasugrel	S	Unknown	Not Reported
	Novorapid	S	Subcutaneous	Not Reported
	Topiramate	S	Unknown	Not Reported
	Glucagen	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Reboxetine	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Ezetimibe	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Endone	S	Unknown	Not Reported
	Ivabradine	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Cholecalciferol	S	Unknown	Not Reported
	5-Methyltetrahydrofolate	S	Unknown	Not Reported
	Cannabis Sativa Oil	S	Unknown	Not Reported
	Mirena	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17743899	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589699		62 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17747147	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200436816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthritis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Indometacin	S	Oral		Not Reported
	Indometacin	S	Oral		Not Reported
	Indometacin	S	Oral		Not Reported
	Indometacin	S	Oral		Not Reported
	Indometacin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17773513	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246919		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S	Unknown	500 Milligrams, Daily, Tablet		Sun
	Plaquenil			S	Unknown	400 Milligrams, Daily		Not Reported
	Lasix 25 Mg Compresse			C	Unknown	25 Milligrams, Daily		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Normix			C	Unknown	Unk		Not Reported
	Dobetin			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Deltacortene 25 Mg Compresse			C	Unknown	Unk		Not Reported
	Pantorc 20 Mg Compresse Gastroresistenti			C	Unknown	20 Milligrams, Daily		Not Reported
	Cardirene 75 Mg			C	Unknown	75 Milligrams, Daily		Not Reported
	Metoprololo			C	Unknown	50 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17804027	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235537		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Behaviour Disorder	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809266	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-025598		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram, Once A Day		Not Reported
	Enoxaparin			S	Subcutaneous	80 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809432	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247759		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809442	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-025271		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Amoxicillin			S	Oral	3 Gram		Aurobindo
	Clavulanic Acid			S	Oral	600 Milligram		Not Reported

	Plaquenil		S	Oral	600 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809472	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019736		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809535	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599814		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Pantoprazole Magnesium	C		Not Reported
	Tenofovir Disoproxil Fumarate	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin D3	C		Not Reported
	Xeljanz	C		Not Reported
	Zopiclone	C		Not Reported
	Atacand Plus	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809571	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599460		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Amoxicillin;Clavulanate Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tridural	C	Unknown	Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809623	EXPEDITED (15-DAY)		OT	HR-ADVANZ PHARMA-GSH201801-000311			Unknown	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Phospholipidosis; Proteinuria; Renal Disorder; Renal Impairment; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	500 Mg, Qd, Tablet		Concordia
	Azathioprine			C		50 Mg, Bid		Not Reported
	Prednisolone			C		10 Mg, Qd		Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809624	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Synthroid	C		Not Reported
	Cymbalta	C		Not Reported
	Hydromorphone	C		Not Reported
	Remicade	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809640	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599612		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809723	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601836		73 YR	Female	CAN

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

Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methyl Salicylate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809833	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247680		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Sun
	Noradrenaline			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cefotaxime Base			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Loxen (Nicardipine Chlorhydrate)			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Plaquenil	S	Oral	Unk		Not Reported
	Hypnovel	C	Unknown	Unk		Not Reported
	Sufentanil	C	Unknown	Unk		Not Reported
	Nimbex	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599524			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809981	EXPEDITED (15-DAY)		OT	ES-ACCORD-182511		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809997	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810101	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598069			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810102	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599579		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	2.0 Dosage Form		Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810198	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598368			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810199	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005434			Unknown	USA

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

Electrocardiogram Qt Prolonged	Hydroxychloroquine		S	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810200	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005435			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810305	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247893		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598506		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810519	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-024941		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Amlodipine+Valsartan Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810579	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598008		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]				
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Simponi		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Humira		S		Not Reported
	Desoximetasone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]			C	Unknown			Not Reported

	Baclofen	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Calcium Gluconate	C	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Gravol	C		Not Reported
	Levaquin	C	Unknown	Not Reported
	Morphine	C		Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Ophthalmic	Not Reported
	Zingiber Officinale	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810788	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

			otherwise specified)			
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methylprednisolone	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	Rectal Gel		Not Reported
	Xeljanz	S	Unknown			Not Reported
	Naproxen	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810800	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599770		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Acetaminophen	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methylprednisolone Acetate	C		Not Reported
	Prednisone	C		Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599854		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Kevzara	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810820	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Glossodynia; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810898	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600537		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	7.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	3.0 Years		Not Reported
	Sulfasalazine			S	Unknown	3.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810909	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599531		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use;	Xeljanz			S	Oral			Not Reported

Rheumatoid Arthritis; Treatment Failure	Xeljanz	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8mg/Kg	Not Reported
	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810910	EXPEDITED (15-DAY)		OT	US-SA-2020SA128509			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Systemic Lupus Erythematosus	Dupixent			S	Unknown	Unk		Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810941	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600279		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 01 Month		Not Reported
	Rituximab			S				Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 609 Days		Not Reported
	Enbrel			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Frequency: Cyclical		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported

Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601296		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	638.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	7.0 Days	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810976	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2598434		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Naproxen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810997	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811009	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601514		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599637		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811141	EXPEDITED (15-DAY)		OT	ES-ACCORD-182600		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811170	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601669		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug	Rituximab			S	Intravenous drip			Not Reported

Intolerance; Intentional Product Use Issue; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	C	Subcutaneous	Not Reported
	Advil [Ibuprofen]	C		Not Reported
	Arava	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Ketorolac	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811317	EXPEDITED (15-DAY)		HO	ES-ACCORD-182419		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Colchicine			S	Oral	1 U Breakfast		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599199		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811632	EXPEDITED (15-DAY)		OT	GB-ACCORD-182513		53 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Nausea	Hydroxychloroquine			S				Not Reported
	Colecalciferol			C		(Not Low Vit D)		Not Reported
	Fluoxetine			C				Not Reported
	Levothyroxine			C				Not Reported
	Cerazette			C				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811798	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise;	Actemra			S	Unknown			Not Reported

Pleurisy; Pneumonia	Arava		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811825	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate Sodium			S	Oral			Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	50 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	150 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Ketoprofen			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prolia Pre-Filled Preservative-Free			C	Subcutaneous			Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811929	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600700		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Rituximab	S	Intravenous drip	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811956	EXPEDITED (15-DAY)		DE, HO	ES-FRESENIUS KABI-FK202004819		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	600 Mg Every 12 Hours		Fresenius Medical Care
	Meropenem (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	1 G Every 8 Hours		Not Reported
	Piperacillin/Tazobactam 4g / 0.5g (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	1 Df Every 8 Hours		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 G Every 8 Hours		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811963	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202005005293			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use; Staphylococcal Infection	Hydroxychloroquine			S		200 Mg Every 12 Hours, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Clarithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601567		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Erythromycin			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Morphine			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812011	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600095			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not	8.0 Months		Not Reported

Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Sleep Disorder Due To General Medical Condition, Insomnia Type	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	5.0 Months	Not Reported
	Gold		S	Unknown	7.0 Months	Not Reported
	Humira		S	Subcutaneous	7.0 Months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	3.0 Years	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Intramuscular		Not Reported
	Sulfasalazine		S	Oral	5.0 Months	Not Reported
	Sulfasalazine		S	Oral	5.0 Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812069	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2020M1049048		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cough; Covid-19; Headache; Intentional Product Misuse; Interstitial Lung Disease; Lung Opacity; Myalgia; Off Label Use; Pyrexia; Respiratory Failure	Prednisone			S		15 Mg Daily		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Four Infusions (375 Mg/M2) Were Weekly		Mylan
	Rituximab			S		Maintenance Therapy; 500 Mg		Mylan
	Hydroxychloroquine Sulfate			S		200 Mg/8 Hour For 10 Days From Day #19		Mylan
	Nebivolol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598046			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812256	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020200777		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Off	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Ceftriaxone			S	Intravenous (not	2 G, Daily		Not Reported

Label Use; Product Use In Unapproved Indication; Respiratory Failure; Thrombocytopenia			otherwise specified)			
	Dexamethasone	S	Intravenous (not otherwise specified)	20 Mg, Daily		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Daily		Not Reported
	Enoxaparine	S	Subcutaneous	80 Mg, Unknown		Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812441	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198949		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	1 Mg/Kg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Roactemra			S		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812551	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020198926		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycine			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported
	Irbesartan Eg			S	Oral	Unk		Not Reported
	Carvedilol Arrow			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	Unk		Not Reported
	Risordan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812607	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049321		86 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Dabigatran			S	Oral	110 Mg/Day X 2		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812616	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049343		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Apixaban			S	Oral	5 Mg/Day X 2		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812622	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049342		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Apixaban			S	Oral	Unk(5 Mg/Day X 2)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812626	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049326		89 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label	Lopinavir/Ritonavir			S		Unk		Not Reported

Use	Apixaban	S	Oral	2.5 Mg/Day X 2		Mylan
	Hydroxychloroquine	S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812696	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131577		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	200 Mg, Qw		Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812701	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131492			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance;	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi

Lymphoma; Neoplasm Malignant; Onycholysis; Tooth Loss	Methotrexate	S			Not Reported
	Sulfasalazine	S			Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C	Oral	100 Mg	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812706	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA131108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous			Not Reported
	Tylenol	C				Not Reported
	Prednisone	C		Unk Unk, Qd		Not Reported
	Prednisone	C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812765	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049416		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	3 Dosage Form, Qd		Mylan
	Lansoprazole			C	Oral	15 Milligram, Qd		Mylan
	Tamiflu			C	Oral	2 Dosage Form, Qd		Mylan
	Augmentin /00756801/			C	Intravenous (not otherwise specified)	3 Gram, Qd		Mylan
	Lovenox			C	Subcutaneous	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812844	EXPEDITED (15-DAY)		OT	ES-ALVOGEN-2020-ALVOGEN-108420		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Fentanyl			S				Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200mg/12h		Not Reported
	Kaletra			S	Oral	5 Ml/12h		Not Reported
	Midazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812879	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-		64 YR	Male	FRA

2020M1049499

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Tercian /00759301/			S	Oral	25 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	200 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	200 Milligram, Bid		Mylan
	Paroxetine			C	Oral	30 Milligram, Qd		Mylan
	Depakine /00228501/			C	Oral	1000 Milligram, Qd		Mylan
	Aerius /01398501/			C	Oral	5 Milligram, Qd		Mylan
	Xanax			C	Oral	0.75 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812925	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599304		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Off Label Use; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813015	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601697		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Vomiting; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813034	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514312		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Pulmonary	Remicade			S	Intravenous (not otherwise specified)			Janssen

Fibrosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Gold		S	Intramuscular	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Leflunomide		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Sulfasalazine		S	Rectal	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813038	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600125		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Celebrex	C		Not Reported
	Diclofenac	C		Not Reported
	Lyrica	C		Not Reported
	Methotrexate	C		Not Reported
	Sulfasalazine	C		Not Reported
	Valsartan	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598767		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601625		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S		Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

	Sulfathalidine			S	Unknown				Not Reported
	Desoximetasone			S	Oral				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Diclofenac			C	Unknown				Not Reported
	Salazopyrin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813289	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600406		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Joint Injury; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813295	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1049663		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tinnitus	Fentanyl			S		Unk		Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)	Unk		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Kaletra			S	Oral	5 Milliliter, Bid (5 Ml/12h)		Mylan
	Midazolam			S		Unk		Mylan
	Hidroxicloroquina /00072601/			S	Oral	200 Milligram, Bid (200mg/12h)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813311	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235960		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Privigen 100mg/Ml Solucion Para Perfusion , 1 Vial De 400 Ml			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Azitromicina (7019a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813329	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1236090		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported

	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;	Teva
	Dexametasona (722a)	S	Intravenous (not otherwise specified)	20 Milligram Daily;	Not Reported
	Enoxaparina (2482a)	S	Subcutaneous	40 Milligram Daily;	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab (8289a)	S			Not Reported
	Dexketoprofeno (7312a)	S	Intravenous (not otherwise specified)	75 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813343	EXPEDITED (15-DAY)		OT	NVSC2020US140080			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Hypothermia; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813420	NON-EXPEDITED			US-PFIZER INC-2020197950			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Off Label Use; Product Use In Unapproved Indication	Zinecard			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813445	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049616		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Amlodipine Besilate/Valsartan			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813449	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238634		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Risedronate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813842	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20200518237		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Tinnitus	Durogesic Matrix			S	Unknown			Janssen
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra			S	Oral	5 Ml/12h		Not Reported
	Midazolam			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	200mg/12h		Not Reported

	Azitromicina	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17814201	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituximab			S	Intravenous drip			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17814262	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238635		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Nausea; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Risedronate Sodium			S	Unknown			Teva
	Risedronate Sodium			S	Oral			Teva
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquinesulfate			S	Unknown			Not Reported
	Hydroxychloroquinesulfate			S	Oral	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17814270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238637		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Risedronate Sodium			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	18251937	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Azithromycin			S	Oral		4 DAY	Not Reported
	Hydroxychloroquine			S	Oral		3 DAY	Not Reported
	Zinc Sulfate			S	Oral		3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	18266213	DIRECT					20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Computerised Tomogram Abnormal; Product Use In Unapproved Indication; Sars-Cov-2 Test Positive	Hydroxychloroquine			S	Oral		2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	18266739	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	18266742	DIRECT		OT			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Plasmapheresis; Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S			1 WEEK	Not Reported
	Levofloxacin			S			1 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	18271950	DIRECT					50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fibrin D Dimer Increased	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported
	Tocilizumab			S		Other Dose:One Dose;		Not Reported
	Ivermectin			S		Other Frequency:One Dose;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	10653444	EXPEDITED (15-DAY)		DS	FR-009507513-1412FRA006146		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Fosamax			S	Oral	Unk		Merck
	Lasilix			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	Unk		Not Reported
	Cacit Vitamine D3			S	Oral	Unk		Not Reported
	Rivotril			S	Oral	Unk		Not Reported
	Avodart			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Inexium (Esomeprazole Magnesium)			S	Oral	Unk		Not Reported
	Salazopyrine			S	Oral	Unk		Not Reported
	Tahor			S	Oral	Unk		Not Reported
	Forlax			S	Oral	Unk		Not Reported
	Skenan			S	Oral	Unk		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Metoject			S	Subcutaneous	Unk		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	12922824	EXPEDITED (15-DAY)		OT	CA-ROCHE-1849821		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Anaphylactic Reaction; Arthralgia; Blood Glucose Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intra-arterial			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Pregabalin	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Urethral	Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Piroxicam	C	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13015664	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865625		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13237837	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893817		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Subcutaneous	Not Reported
	Voltaren [Diclofenac]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13538108	EXPEDITED (15-DAY)		OT	CA-ROCHE-1933679			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Endocervical			Not Reported
	Vioxx			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13614636	EXPEDITED (15-DAY)		DS	CA-ROCHE-1942553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Ibuprofen;Phenyle			S	Unknown			Not Reported

	phrine Hydrochloride			
	Cetirizine Hydrochloride;Ibuprofen;Phenylephrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Kevzara	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Topicorte	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
	Salazopyrina	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13628309	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20170602995		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Avara	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15157332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2155675			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Off Label Use; Pneumonia; Pneumonia; Treatment Failure	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15369246	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181844		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Pneumonia; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringemide		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Cephalexin [Cefalexin]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15372794	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2182468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	16739745	EXPEDITED (15-DAY)		OT	DE-ACCORD-152811			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1 - 1 - 1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1 - 0 - 1) 2.5 Mg Twice Daily		Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported

Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
Apixaban	S		2.5 Milligram, Bid	Not Reported
Trospium Chloride	S		30 Mg, Qd Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Omeprazole	S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Not Reported
Apixaban	S		2.5 Milligram, Bid	Not Reported
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Ramipril	S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Accord
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	16884438	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418381			Female	CAN

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

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz Xr	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Hydroxychloroquine	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17288297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2522989		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporin A			S	Unknown			Not Reported
	Depo-Provera			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Infliximab	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Naprosyn [Naproxen]	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17620330	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002212			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Infection	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Aminosalicylic Acid			S		81 Mg, Qd		Not Reported
	Aminosalicylic Acid			S				Not Reported
	Mycophenolate Mofetil			S		1 G, Qd		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Quinacrine			C		100 Mg, Qd		Not Reported
	Quinacrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17682088	EXPEDITED (15-DAY)		OT	DE-ACCORD-179153		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral	Intermittent Usage		Not Reported
	Sulfasalazine			S	Oral	Strength 500 Mg		Not Reported
	Prednisolone			S	Oral	Intermittent Usage Of Low-		Not Reported

				Dose Prednisolone. Also Received 30 Mg, 7.5 Mg, 5 Mg, 40 Mg, 20 Mg, 10 Mg	
	Prednisone	S		Increased To	Not Reported
	Metoprolol	C			Not Reported
	Amlodipine	C			Not Reported
	Prednisone	S			Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral	Two Weeks Before Presentation	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17746486	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine			S		400 Mg, Qd		Not Reported

	Phosphate]				
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tofacitinib Citrate	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17761776	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202003004184			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hospitalisation; Off Label Use; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			C		Unknown		Not Reported
	Biguanides			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17763474	EXPEDITED (15-DAY)		HO	US-ROCHE-2594510		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Deep Vein Thrombosis; Intentional Product Use Issue; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enoxaparin			C				Not Reported
	Oxygen			C				Not Reported
	Loperamide			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Zosyn			C				Not Reported
	Tylenol			C				Not Reported
	Vancomycin			C				Not Reported
	Zithromax			C				Not Reported

	Calcium Gluconate	C	Not Reported
	Potassium Chloride	C	Not Reported
	Cholecalciferol	C	Not Reported
	Melatonin	C	Not Reported
	Multivitamin And Mineral	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17767076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594973		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Advil [Ibuprofen]			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17769513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778024	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine	S	Oral			Not Reported
	Prednisone	C	Oral			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Tofacitinib Citrate	C	Oral	Extendedrelease		Not Reported
	Infliximab	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778065	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778124	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505936		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Oral			Not Reported

Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Celebrex	S	Unknown	2 Dosage Forms	Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Sulfasalazine	S	Rectal		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine /00072603/	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17780182	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505924		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17780358	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505849		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse	Remicade			S	Intravenous (not			Janssen

Reaction; Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis			otherwise specified)		
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17782408	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-181852		26 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Off Label Use; Suicide Attempt	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Allopurinol			C	Oral	100 Mg Tablet		Not Reported
	Paracetamol			C	Oral			Not Reported
	Famotidine			C	Oral	20 Mg Tablet		Not Reported
	Doxazosin			C	Oral			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2,000 Mg Injection Iv		Not Reported
	Cefixime/Cefixime Trihydrate			C	Oral			Not Reported
	Magnesium Chloride Anhydrous			C	Oral	53 Mg Coated Tablets		Not Reported
	Prednisone			C	Oral			Not Reported
	Carvedilol/Carvedilol Hydrochlodride			C	Oral	25 Mg Tablet		Not Reported
	Zemplar			C	Oral	1 Microgram Soft Capsules		Not Reported
	Myfortic			C	Oral	360 Mg Gastro-Resistant Tablets		Not Reported
	Enoxaparin			C	Subcutaneous	20 Mg (2,000 Iu) Injection 0.2 Ml		Not Reported
	Fosrenol			C	Oral			Not Reported

	Metamizole Sodium	C	Oral	575 Mg Capsule	Not Reported
	Tacrolimus	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Tacrolimus	C	Oral		Not Reported
	Tacrolimus	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17791629	EXPEDITED (15-DAY)		DE	ES-ACCORD-181888		84 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxychloroquine			S	Oral	400 Mg Loading Dose Followed By 200 Mg / Day		Not Reported
	Azithromycin			C	Oral			Not Reported
	Hydroxychloroquine			S	Oral	Loading Dose Of 400 Mg Every 12 Hours Followed By 200 Mg Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17800794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187427		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17807175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598861		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported

Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency; Weight Decreased; Weight Increased	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Depo-Medrol	C		Not Reported
	Diamicron	C	Unknown	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Ebastine	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17809339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2026232		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Rituximab			S	Unknown	Therapy Duration: 4 Years		Not Reported

Ineffective; Hypertension; Off Label Use; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Therapy Duration: 155 Days	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 519 Nos	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Valsartan	C			Not Reported
	Cortisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Hydromorphone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17811582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599879		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17812560	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050635			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral			Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram		Not Reported
	Ceftriaxon			C	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17812589	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020198870		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Symbicort Turbohaler			S	Respiratory (inhalation)	2 Df, 3x/Day(2-2-2; 2df/8 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2 Df, 3x/Day(2-2-2 Inh)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601674			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Off Label Use; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814348	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006311			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Methotrexate			S	Oral	175 Mg, Weekly		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814398	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202005005520			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814418	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598071			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Cirrhosis; Off Label Use; Synovitis; Treatment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Failure; X-Ray Abnormal	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814475	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597810			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814516	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597952		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

Intolerance; Fatigue; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure	Apo-Leflunomide	S	Oral	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814573	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599215		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density	Actemra			S	Unknown			Not Reported

Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C		Not Reported
	Pantoprazole Magnesium	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599622		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema;	Actemra			S	Intravenous (not otherwise specified)	365.0		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	366.0		Not Reported
	Arava			S	Oral	366.0		Not Reported
	Enbrel			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous	3.0 Months		Not Reported

Infection; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Rash; Syncope; Urticaria	Humira	S	Subcutaneous	366.0	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown	16.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	638.0	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	8.0 Years	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	396.0	Not Reported
	Xeljanz	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Prevacid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814607	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599715		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Frequency: Cyclical		Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 6.0 Months		Not Reported
	Prednisone			S	Unknown			Not Reported

Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
Asa	C	Unknown	Not Reported
Bisoprolol	C	Unknown	Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
Endocet	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Indomethacin [Indometacin]	C		Not Reported
Macrogol	C		Not Reported
Metoprolol	C	Unknown	Not Reported
Naproxen Sodium	C	Unknown	Not Reported
Pennsaid	C	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

Erythematosus; Wound	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814651	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602457			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814669	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602466		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814706	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814711	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA131305		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Ilaris			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814864	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES-1239014		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intrusive Thoughts; Suicide Attempt	Hidroxicloroquina (2143a)			S	Oral	200mg Every 12 Hours		Teva
	Levofloxacino (2791a)			C	Unknown			Not Reported
	Cortic - Corticoide			C	Intravenous bolus	Bolus Corticosteroids Iv		Not Reported
	Septrin			C	Unknown			Not Reported
	Kaletra			C	Oral			Not Reported
	Acetilcisteina (233a)			C	Unknown			Not Reported
	Ciclosporina (406a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814963	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601285		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814968	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600417			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815016	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		2 Df, Qd (Dose: 200 Mg)		Sanofi
	Methotrexate			S	Unknown	1 Df, Qw		Not Reported
	Methotrexate			S	Unknown	1 Df, Qw		Not Reported

Leflunomide	S		1 Df, Qd		Sanofi
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Enbrel	S		1 Df, Qw		Not Reported
Actemra	S				Not Reported
Xeljanz	C				Not Reported
Sulfasalazine	C				Not Reported
Wellbutrin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815025	EXPEDITED (15-DAY)		OT	NVSC2020GB043308		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Mg		Not Reported
	Prednisolone			S				Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602428		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Intolerance; Fibromyalgia; Intentional Product Use Issue; Nausea; Oedema; Off Label Use; Rheumatoid Arthritis; Synovitis; Underdose; Vomiting				otherwise specified)	
	Celebrex		S	Unknown	Not Reported
	Celebrex		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S		Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Naproxen		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815068	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0123276			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alprazolam			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602524		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Pressure Increased; Dermatomyositis; Diarrhoea; Drug Ineffective; Foot Fracture; Infusion Related Reaction; Migraine; Off Label Use; Pain In Extremity; Poor Venous Access; Post-Traumatic Neck Syndrome; Rhinorrhoea; Road Traffic Accident; Thrombophlebitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diflucan			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Euro D			C				Not Reported
	Leucovorin [Folinic Acid]			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Sulfamethoxazole;Trimipramine			C				Not Reported
	Zoplicone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598423		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815201	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114144		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus	Desoximetasone			S	Oral			Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Diclofenac Sodium			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S		Unk		Not Reported
	Folic Acid			S		5 Mg, Qd		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Alendronate Sodium			S				Not Reported
	Cortisone Acetate			S				Not Reported

Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Cetirizine Hydrochloride	S			Not Reported
	Actemra	S			Not Reported
	Cimzia	S			Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfathalidine	S			Not Reported
	Xeljanz	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815212	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-014626			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral	Prednisolone			S	Unknown			Bausch And Lomb
	Glyceryl Trinitrate			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Colecalciferol			S	Unknown			Not Reported
	Ezetimibe			S	Unknown			Not Reported
	Ivabradine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Prasugrel			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported

Tonsillitis	Reboxetine	S	Unknown	Not Reported
	Sildenafil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Endone	S	Unknown	Not Reported
	Glucagen	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Mirena	S	Unknown	Not Reported
	Novorapid	S	Unknown	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599760		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown	9.0 Years		Not Reported

Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate	S	Unknown	9.0 Years	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	12.0 Months	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	2.0 Months	Not Reported
	Xeljanz	S	Oral	2.0 Months	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Paracetamol	C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815260	EXPEDITED (15-DAY)		DS, OT	CA-SAKK-2020SA115119AA		43 YR	Female	CAN

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

Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S			Sanofi
	Desoximetasone	S			Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Topicort	S	Subcutaneous		Sanofi
	Topicort	S			Sanofi
	Topicort	S	Oral	Unk	Sanofi
	Prednisone	S			Not Reported
	Arava	S	Oral	20 Mg	Sanofi
	Arava	S	Oral	Unk	Sanofi
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cetirizine Hydrochloride	S		20 Mg	Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Folic Acid	S	Oral	1 Mg	Not Reported
	Folic Acid	S	Oral	5 Unk	Not Reported
	Folic Acid	S		1 Unk	Not Reported
	Folic Acid	S		5 Unk	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine	S		400 Unk	Sanofi
	Hydroxychloroquine	S		Unk	Sanofi
	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	40 Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Sanofi
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported

Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Intra-arterial	25 Unk	Not Reported
Paracetamol	S			Not Reported
Plaquenil	S		400 Mg, Qd	Sanofi
Plaquenil	S		40 Unk	Sanofi
Plaquenil	S	Oral	40 Unk	Sanofi
Prednisone	S			Not Reported
Prednisone	S			Not Reported
Sarilumab	S			Sanofi
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Leflunomide	S	Oral		Sanofi
Leflunomide	S	Oral		Sanofi
Pseudoephedrine Hydrochloride	S			Sanofi
Pseudoephedrine Hydrochloride	S		25 Mg	Sanofi
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Oral	25 Mg	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S			Not Reported
Cimzia	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	4 Mg	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S				Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk		Not Reported
Stelara	S				Not Reported
Sulfathalidine	S				Not Reported
Sulfathalidine	S	Subcutaneous	Unk		Not Reported
Tofacitinib Citrate	S	Subcutaneous			Not Reported
Tofacitinib Citrate	S		Unk		Not Reported
Xeljanz	S				Not Reported
Cortisone Acetate	S	Topical	25 Mg		Not Reported
Acetaminophen	S				Not Reported
Reactine [Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride]	S		10 Mg		Not Reported
Reactine [Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride]	S		20 Unk		Not Reported
Atasol [Paracetamol]	C				Not Reported
Salazopyrin	C				Not Reported
Tofacitinib Citrate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815461	EXPEDITED (15-DAY)		DE, OT	CA-ROCHE-2600163		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Doxycycline	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Simponi	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815481	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237783		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815499	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600237			Female	CAN

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

Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815502	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600347			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597636			Female	CAN

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

Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Off Label Use; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815637	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported

	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815690	DIRECT	Y	LT			93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Therapy Cessation	Hydroxychloroquine Sulfate			S	Oral			Sandoz
	Acetaminophen 650 Mg			C				Not Reported
	Albuterol Mdi			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Benzonatate 100 Mg			C				Not Reported
	Finasteride 5mg			C				Not Reported
	Guaifenesin -La 600mg			C				Not Reported
	Heparin 5000 Units			C				Not Reported
	Hydrocodone/Homatropine Syrup			C				Not Reported
	Metoprolol Succinate 100 Mg			C				Not Reported
	Morphine 1 Mg Ivp			C				Not Reported
	Tamsulosin 0.4mg			C				Not Reported
	Piperacillin/Tazobactam 3.375 Gm Ivpb			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815728	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600346			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Simponi	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598500		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Prednisone			C	Oral	1 Every 1 Days		Not Reported
	Prednisone			C	Oral	1 Every 1 Days		Not Reported
	Xeljanz			C	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label	Rituximab			S	Unknown			Not Reported

Use; Rheumatoid Arthritis	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815890	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2597924			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported

	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Subcutaneous	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Acetonide	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815918	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600989		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600622		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Zostavax	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815968	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599481		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Benign Neoplasm; Bladder Operation; Disability; Drug Ineffective; Fatigue; Headache; Influenza Like Illness; Malaise; Off Label Use; Peripheral Swelling; Spinal Pain; Urinary Tract Infection; Vaginal Haematoma	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	6.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	105.0 Days		Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported

	Ergocalciferol	C	Oral	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602954		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816143	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1238595		61 YR	Female	FRA

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

Electrocardiogram Qt Prolonged	Amoxicilline Trihydratee		S	Oral	Teva
	Clavulanique (Acide)		S	Oral	Not Reported
	Plaquenil		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816150	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603071		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tofacitinib Citrate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816368	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600951		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816376	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598424		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816378	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1237799		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Tacrolimus	S	Unknown	6 Dosage Forms Daily;		Not Reported
Tacrolimus	S	Unknown	5 Dosage Forms Daily;		Not Reported
Prednisone	C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816425	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238156		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm	Azathioprine			S	Unknown			Not Reported

Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline	S	Unknown	Actavis
	Methotrexate	S	Subcutaneous	Barr
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600223		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Endocervical			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816694	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601297		77 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816728	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020202244		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Off Label Use; Product Use Issue	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Inhixa			C	Subcutaneous	40 Mg		Not Reported
	Sirtap			C	Intravenous (not otherwise specified)	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816729	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200441		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Tazocilline			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816748	EXPEDITED (15-DAY)		OT	NVSC2020GB054189		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis
	Hydroxychloroquine			S				Novartis
	Clopidogrel			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Warfarin			S				Not Reported
	Atorvastatin			S	Unknown	High Dose		Not Reported
	Atorvastatin			S				Not Reported
	Atorvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816759	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816805	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020202843		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Dizziness; Ear Discomfort; Erythema; Fatigue; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Muscle Spasms; Nausea; Rheumatoid Arthritis; Vomiting	Atorvastatin Calcium			S	Unknown	10.0 Mg, 1x/Day		Pfizer
	Bisoprolol			S	Unknown	2.5 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg		Not Reported
	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
	Sandostatin			S	Intramuscular	20 Mg 4 Every 1 Week		Not Reported
	Sandostatin			S	Subcutaneous	50 Ug Total		Not Reported
	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5.0 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816921	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1238603		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Asthenia; Chest Discomfort; Drug Ineffective; Dyspnoea; Headache; Heart Rate Increased; Hyperhidrosis; Left Ventricular Dilatation; Myocarditis; Nausea;	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Oral	2000 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Milligram Daily;		Not Reported
	Colchicine			C	Unknown	.6 Milligram Daily;		Not Reported

Nephritis; Pleuritic Pain; Systemic Lupus Erythematosus; Treatment Failure; Vasculitis	Naproxen		C	Unknown	500 Milligram Daily;	Not Reported
	Prednisone		C	Unknown	50 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816922	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238103		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	2.8571 Milligram Daily; 40 Mg, 1 Every 2 Weeks		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816944	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600620			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816994	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1047833		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Anakinra			S	Subcutaneous	100 Milligram		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg Dia		Mylan
	Tocilizumab			S				Mylan
	Tocilizumab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817030	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004686			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngitis; Sinus Disorder	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Xeljanz			S	Oral	5 Mg, Bid (5mg 1 Tablet By Mouth Twice A Day)		Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817236	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505926		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817261	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603030		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Contraindicated Product Administered	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown	Extended Release		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Loperamide Hydrochloride	C	Unknown		Not Reported
	Nasonex	C	Unknown	Metered Dose	Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Tylenol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817265	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817283	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1050069		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Vomiting	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Bid		Not Reported
	Naloxone/Oxycodone			S	Oral	10 Milligram, Bid		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	Unk		Mylan
	Prolia			C	Subcutaneous	Unk		Mylan
	Stilnox			C	Oral	10 Milligram, Qd		Mylan
	Pantoprazol /01263201/			C	Oral	20 Milligram, Qd		Mylan
	Calcium Carbonate W/Colecalciferol			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817285	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817287	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817430	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051273			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram		Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Tocilizumab	S			Not Reported
	Dexketoprofen	S	Intravenous (not otherwise specified)	25 Milligram Every 8 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601342		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

	Calcium Carbonate	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Imitrex [Sumatriptan]	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817551	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1238086		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Exposure During Pregnancy; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aamitriptyline			C	Unknown	10 Milligram Daily;		Not Reported
	Azithromycin			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown			Not Reported
	Gabapentin			C	Unknown	400 Milligram Daily;		Not Reported
	Metonia			C	Unknown			Not Reported
	Prednisone			C	Unknown	8 Milligram Daily;		Not Reported
	Ranitidine			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238074		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817621	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238124			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817647	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238602		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

	Bacillus Calmetteguerin Bcg	C	Unknown	Not Reported
	Bacillus Calmetteguerin Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817829	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238072		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817869	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr

Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Actemra		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817873	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238139			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine			S	Oral	200 Milligram Daily;		Not Reported
	Leucovorin Calcium			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram Daily;		Not Reported
	Ketoprofen			S	Topical			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prevnar 13			S	Intramuscular			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817875	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238166			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthritis; Synovitis; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Teva
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Sulfamethoxazole And Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817915	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1239120		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Tacrolimus		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818373	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601993		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Therapeutic Product Effect Decreased	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Lyrica		C	Oral	Not Reported
	Prednisone		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818499	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1239114		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818723	NON-EXPEDITED			NVSC2020US141219			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Iron Overload	Jadenu			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818940	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602354		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel		S	Subcutaneous	Therapy Duration: 2.0 Years	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818965	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605839		40 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	12304140	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1745534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported

Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown	25 Mbq	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	And 5 Mg	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	25 Mg (For 11 Years)	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	11 Months	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Not Reported
	Topicort [Desoximetasone]	S		Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17042389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2464645		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Humira	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Methotrexate	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17063042	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17721471	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1227414		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	2-3 Cp Per Day:400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17804815	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3410200-00		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Azitromicina			S	Unknown			Not Reported

	Metilprednisolona	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818446	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602195		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818450	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Cellcept [Mycophenolate Mofetil]			S	Unknown	Therapy Duration: 61.0		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Myfortic	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818458	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601809		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818807	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3414053-00		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598521		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated;	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wheezing	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818879	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818888	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601616		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Off Label Use; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Leflunomide	C			Not Reported
	Naproxen	C			Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819015	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598559		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone	Actemra			S	Unknown			Not Reported

Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819081	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819232	EXPEDITED (15-DAY)		OT	BN-ACCORD-182780		67 YR	Male	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Hydroxychloroquine			S		400 Mg Twice Daily Day-1 And 200 Mg Twice Daily Day-2 To 5		Not Reported
	Lopinavir/Ritonavir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819257	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599836		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819335	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004005747			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Pain In Extremity; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk, Citrate Free (1 In 2 Wk)		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819381	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1239130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr

	Minocycline	S	Unknown		Actavis
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819383	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601269		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Gait Disturbance; Multiple System Atrophy; Off Label Use; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Oral			Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601291		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S				Not Reported
	Folic Acid			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported

	Arava	S	Oral	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Fosamax	S	Intracavernous	Not Reported
	Fosamax	S		Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606795		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported

Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported
Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	18251903	DIRECT		DE, HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Electrocardiogram Qrs Complex Prolonged; Haemolysis; Hypercapnia; Hyperkalaemia; Hyperthermia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Pericarditis; Rhabdomyolysis; Tachycardia	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17350897	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Atrovent			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Flovent	S	Unknown	Not Reported
	Albuterol Sulfate And Ipratropium Bromide	S	Unknown	Not Reported
	Lasix [Furosemide Sodium]	S	Unknown	Not Reported
	Lipitor	S	Unknown	Not Reported
	Losec [Omeprazole Magnesium]	S	Oral	Not Reported
	Metformin	S	Oral	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Atorvastatin Calcium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17819810	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605534		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Off Label Use; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17819817	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	12855891	EXPEDITED (15-DAY)		HO	CA-ROCHE-1842514		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration: 6 Days		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 731.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 731.0		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	13161522	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-2016047597		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Enthesopathy; Erythema; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity;	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Adalimumab			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	.6 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Golimumab			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous drip	400 Milligram		Not Reported
	Sulfasalazine			S	Endocervical			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Hypersensitivity; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Ustekinumab	S	Subcutaneous		Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Abatacept	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	6 Dosage Forms	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Celebrex	S	Oral	200 Milligram	Not Reported
	Codeine	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous drip		Not Reported

Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
Rituximab	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Oral	4 Dosage Forms	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Apo Ibuprofen	S	Oral	600 Milligram	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Colchicine	C	Oral	.6 Milligram	Not Reported
Folic Acid	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Forms	Not Reported
Methotrexate Sodium	C	Unknown	10 Milligram	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Methotrexate Sodium	C	Unknown	2.5 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram Er	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram Er	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Uloric	C	Oral	160 Milligram	Not Reported
Uloric	C	Oral	80 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported

Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Febuxostat	C	Unknown	160 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Vitamin D3	C	Oral	2000 Iu (International Unit)	Not Reported
Xeljanz	C	Unknown		Not Reported
Cannabis Sativa	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	13182650	EXPEDITED (15-DAY)		OT	CA-ROCHE-1747445		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Viral Upper Respiratory Tract Infection	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	C	Oral	On Hold	Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	14763969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104641		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	15237821	EXPEDITED (15-DAY)		CA, DE	DE-ROCHE-2162345			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Clexane			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 200 Mg, Frequency: Once Daily From		Not Reported
	Heparin Lmw			S	Transplacental			Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 100 Mg, Frequency: Once Daily100 Mg		Not Reported
	Enoxaparin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	From Gestational Week 0-113+6		Not Reported
	Prednisolon [Prednisolone]			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 10 Mg, Frequency: Every 2 Days From		Not Reported

Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S			Not Reported
Pantozol [Pantoprazole Sodium Sesquihydrate]	S	Transplacental	From Gestational Week 0-14therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 40 Mg, Fr	Not Reported
Quensyl	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 400 Mg, Frequency: Once Daily	Not Reported
Salbutamol	S	Transplacental	Frequency: Daily From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental		Not Reported
Rituximab	S	Transplacental		Not Reported
Rasilez	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 17/Jan/2012 Dose: 300 Mg, Frequency: Once Daily	Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Novaminsulfon	S	Transplacental		Not Reported
Delix [Ramipril]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 20 Mg, Frequency: Once Daily	Not Reported
Torem [Torasemide]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date:	Not Reported

				20/Mar/2012 Dose: 100 Mg, Frequency: Once Daily From	
	Advagraf	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 6 Mg, Frequency: Once Daily	Not Reported
	Simvastatin	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 From Gestational Week 0-14	Not Reported
	Cytotec	C	Transplacental	Start Date And Cessation Date: 20/Mar/2012	Not Reported
	Cyclophosphamide	C	Transplacental	3000 Mg Cumulative Start Date, Cessation Date: /Aug/2011	Not Reported
	Mifegyne	C	Transplacental	Start Date And Cessation Date: 20/Mar/2012	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	15247879	EXPEDITED (15-DAY)		DE, HO	CA-ROCHE-2164538		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Sulfasalazine	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

	Cannabis Sativa	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Lyrica	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	16808742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2402077		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17317853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529157		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Hypersensitivity; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	Neurontin			C	Unknown			Not Reported
	Premarin			C				Not Reported

	Tylenol	C	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Aluminium Acetate	C		Not Reported
	Benzethonium Chloride	C		Not Reported
	Ergocalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17772750	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2020187436		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg		Pfizer
	Propranolol			S	Oral	20 Mg, Every 12 Hours		Not Reported
	Laroxyl			S	Oral	15 Drop, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Every 12 Hours		Not Reported
	Paracetamol			C	Oral	Unk Unk, As Needed		Not Reported
	Pantoprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Oxygen			C	Respiratory (inhalation)	1 L, Every 1 Minute		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17810040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005315			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17811826	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005312			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Septic Shock	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17811877	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005316			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Reperfusion Injury	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17811905	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005343			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Reperfusion Injury	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601477		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Wellbutrin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Risedronate	C	Oral		Not Reported
	Ergocalciferol	C	Unknown	4000 Iu (International Unit)	Not Reported
	Celebrex	C	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Bupropion	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820095	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1239435		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalitis; Enterovirus Infection; Off Label Use	Prednisolone			S	Unknown			Actavis
	Prednisolone			S	Unknown	In July 2017 At The Time Of Presentation For The 1st Time		Actavis
	Prednisolone			S	Oral	In 2018, At The Time Of Flare Of Sle Administered After Methylprednisolone		Actavis
	Prednisolone			S	Oral	Final Dose After Tapered Down By 5mg/Week		Actavis
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	In July 2017 At The Time Of Presentation For The 1st Time; Later Discontinued		Not Reported

Mycophenolate Mofetil	S	Unknown	After Azathioprine Was Stopped; Therapy Stopped In 2018 After 2en Enterovirus Event	Teva
Hydroxychloroquine	S	Unknown		Not Reported
Rituximab	S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart	Not Reported
Rituximab	S	Other	First Dose: 2g/Kg Body Weight; Second Dose After 2 Weeks: 1g Infusion In 2 Doses 14 Days Apart	Not Reported
Immunoglobulins Nos	S	Intravenous (not otherwise specified)	2 G/Kg	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)		Not Reported
Aciclovir	C	Intravenous (not otherwise specified)		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820175	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602385		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate Sodium	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Naproxen	C		Not Reported
Prednisone	C		Not Reported
Tofacitinib Citrate	C		Not Reported
Viread	C		Not Reported
Amlodipine	C		Not Reported
Arava	C		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600455			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820234	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600299		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Gastrointestinal Disorder; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Lip Ulceration; Mobility Decreased; Mouth Ulceration;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Tuberculin Test Positive; Urinary Tract Infection	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Gold	C	Unknown	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602932		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Desoximetasone	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Winpred	S	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820305	EXPEDITED (15-DAY)		DS	CA-ROCHE-1664109		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Voltaren [Diclofenac]			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820341	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167460		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hypertension; Joint Swelling; Loss Of	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820384	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-025850		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Kaletra			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Interferon Beta			S	Unknown	250 Milligram, Every Other Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820447	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-026176		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Shock	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Lopinavir;Ritonavir		S	Oral	Unk	Not Reported
	Methylprednisolone		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820557	EXPEDITED (15-DAY)		OT	NVSC2020US140984			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: Unknown		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Fentanyl			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Lidocaine			S	Transplacental	Maternal Dose: 2 Percent		Not Reported
	Prostacyclin			S	Transplacental	Maternal Dose : Unknown		Not Reported
	Bupivacaine			S	Transplacental	Maternla Dose: Unknown		Not Reported
	Morphine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Heparin			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Epinephrine			S	Transplacental	Maternal Dose: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820565	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Decreased	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820644	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599668		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

	Topicorten	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Leflunomide	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820691	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020202532		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial Neuralgia; Fatigue; Groin Pain; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness;	Atorvastatin Calcium			S	Unknown	10 Mg, 1x/Day		Pfizer
	Bisoprolol			S	Unknown	2.5 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg		Not Reported
	Sandostatin			S	Subcutaneous	Unk		Not Reported
	Sandostatin Lar			S	Intramuscular	30 Mg, Monthly		Not Reported
	Sandostatin Lar			S	Intramuscular	30 Mg, Monthly		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5 Mg, 1x/Day		Not Reported

Labyrinthitis; Muscle Spasms; Nausea; Rheumatoid Arthritis; Visual Impairment; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820782	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020200464		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820787	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200440		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Quetiapine Arrow			S	Oral	100 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820788	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020202119		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Maternal Exposure During Pregnancy; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Thrombocytopenia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Fer [Ascorbic Acid;Ferrous Chloride]			C		Unk		Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820792	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200453		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601806		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Unevaluable Event	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S		Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820804	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020202121		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820851	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020202110		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg		Pfizer
	Zithromax			S	Oral	250 Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg		Not Reported
	Esidrex			C		Unk		Not Reported
	Rocephine			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821010	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020200438		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycine Pfizer			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821037	EXPEDITED (15-DAY)		OT	CA-ROCHE-1957024		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 7 Months		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 10 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 2 Years		Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Therapy Duration: 4 Days		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported

Atorvastatin Calcium	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821038	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020204019		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Product Use In Unapproved Indication	Zitromax Avium			S	Oral	1 Df, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2 Df, 1x/Day		Not Reported
	Kaletra			S	Oral	4 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821065	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599160		51 YR	Female	CAN

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

	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821119	EXPEDITED (15-DAY)		OT	US-HORIZON-PRE-0167-2020			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821167	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)					
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821230	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598798		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Cannabis Sativa			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821422	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598993		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Alendronate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Parenteral	Not Reported

Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821532	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000130			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Hypothermia; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported
	Propofol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821576	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000132			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821661	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000133			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	18272939	DIRECT					80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lopinavir-Ritonavir			S	Oral	Other Dose:800/200 Mg;	6 DAY	Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Eculizumab			S	Oral	Other Frequency:2 Doses;		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	18272977	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cytopenia; Leukocytosis; Neutrophilia; Off Label Use	Lopinavir-Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Eculizumab			S				Not Reported
	Ceftriaxone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	18273022	DIRECT					90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cytopenia; Leukocytosis; Neutrophilia; Off Label Use	Lopinavir-Ritonavir			S				Not Reported
	Lopinavir-Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Eculizumab			S	Oral	Other Frequency:2 Doses; Other Route:Iv		Not Reported
	Ceftriaxone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	12842433	EXPEDITED (15-DAY)		OT	CA-ROCHE-1841433		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Every 24 Hrs		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	13147472	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840907			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	8x 2.5 Mg Tablets		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 370.0 Day(S)		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	14692329	EXPEDITED (15-DAY)		OT	US-UCBSA-2018012947			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Tuberculosis	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	15384496	EXPEDITED (15-DAY)		HO	CA-ROCHE-2181774		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	16079901	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05867			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)		
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Liquid Intramuscular	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous, Dose- Unknown	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown.	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular, Dose- Unknown	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	16645866	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Plaquenil			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Diclofenac Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17090518	NON-EXPEDITED			US-UCBSA-2018026206			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Rash	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Injection		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17218475	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2019SP013302		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Confusional State; Headache; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Neck Pain; Off Label Use; Photophobia; Pyrexia; Speech Disorder; Viral Upper Respiratory Tract Infection; Vomiting	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Milligram		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram Per Day		Not Reported
	Prednisolone			S	Oral	40 Milligram		Not Reported
	Prednisolone			S	Unknown	Weaned By 5 Mg Per Week To 5 Mg Daily		Not Reported

	Rituximab	S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1 G Infusion In 2 Doses 14 Days Apart	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17465267	EXPEDITED (15-DAY)		OT	IT-ROCHE-2556901		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Envarsus			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Rituximab			C	Unknown	Unk		Not Reported

	Methylprednisolone	C	Unknown	Unk (Pulses)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17559409	EXPEDITED (15-DAY)		DS	CA-ROCHE-2568722		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indocid [Indometacin]			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Gold (198 Au) Colloidal			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Cymbalta	C	Oral		Not Reported
	Folic Acid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17694944	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2020-011287		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum Infection	Prednisolone			S	Oral	Permanent 1-0-0		Not Reported
	Prednisolone			S	Oral	Intermittent Usage; Low-Dose; Two Weeks Before Presentation		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Intermittent Usage 1-0-0		Not Reported
	Sulfasalazine			S	Oral	2-0-2		Not Reported
	Hydroxychloroquine			S	Oral	1-0-1		Not Reported
	Metoprolol			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17705408	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2020165611		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	2 Df, 2x/Day		Pfizer
	Prednisolone			S		Unk(Intermittent Usage Of Low-Dose Prednisolone)		Not Reported

	Prednisolone	S		20 Mg	Not Reported
	Leflunomide	S	Oral	10 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	40 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	30 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	20 Mg, 1x/Day(Two Weeks Before Presentation)	Not Reported
	Prednisone	S	Oral	20 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	15 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	10 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	7.5 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	4 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, 2x/Day	Not Reported
	Metoprolol	C		Unk	Not Reported
	Amlodipine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17733953	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17743772	EXPEDITED (15-DAY)		HO, OT	IT-VIIV HEALTHCARE LIMITED-IT2020073217		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Off Label Use; Oral Disorder; Rash Pruritic; Rash Pustular; Rash Vesicular; Stevens-Johnson Syndrome	Abacavirsulphate+Dolutegravir+Lamivudine			S	Oral	1 Df, Qd		Viiv
	Symtuza			S	Oral	1 Df, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17749010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590697		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 365.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 6.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; X-Ray Abnormal	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Therapy Duration: 365.0	Not Reported
	Orencia		S	Unknown	Therapy Duration: 365.0	Not Reported
	Prednisone		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Desoximetasone		S	Unknown		Not Reported
	Desoximetasone		S	Oral		Not Reported
	Pantoprazole		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17749983	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010469		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Humira	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	1 Ml, Q.Wk.		Not Reported
	Prednisone	C	Unknown	7 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17764352	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3398690-00		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Lopinavir/Ritonavir			S	Oral			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Piperacillina/Tazobactam			C				Not Reported
	Inhixa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17776898	EXPEDITED (15-DAY)		DE, OT	DE-ACCORD-181640		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure	Hydroxychloroquine			S	Oral	200 Mg 1-0-1		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Strength: 500 Mg ,1-0-0		Not Reported
	Azithromycin			C				Not Reported
	Piperacillin Sodium/Tazobactam Sodium			C				Not Reported
	Tazobac			C				Not Reported
	Atorvastatin			C				Not Reported
	Meropenem			C				Not Reported

	Apixaban			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17787494	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1878868		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Celecoxib	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Apo-Gabapentin	C	Unknown	Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Atorvastatin Calcium	C	Oral	Not Reported
Atorvastatin Calcium	C	Unknown	Not Reported
Cipralex [Escitalopram]	C	Unknown	Not Reported
Cipralex [Escitalopram]	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Escitalopram	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported
Gabapentin	C	Oral	Not Reported

Hydrochlorothiazide	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Oral	Not Reported
Hydromorphone Hydrochloride	C	Oral	Not Reported
Mupirocin	C	Topical	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Shark Liver Oil	C	Unknown	Not Reported
Tapentadol Hydrochloride	C	Unknown	Not Reported
Taro-Mupirocin	C	Topical	Not Reported
Tramacet	C	Oral	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Estrace	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822140	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602951		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822233	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-025339		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Electrocardiogram Qt Prolonged	Amiodarone Arrow 200mg Scored Tablets			S	Oral	200 Milligram		Aurobindo
	Plaquenil			S	Oral	600 Milligram		Not Reported
	Zithromax			S	Oral	1 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822404	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02333		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Exposure During Pregnancy; Foetal Death; Foetal Growth Restriction; Hypertension; Pre-Eclampsia; Thrombotic Microangiopathy; Weight Increased	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822412	EXPEDITED (15-DAY)		OT	CH-TEVA-2020-CH-1239230		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	800 Milligram Daily;		Teva
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Atazanavir			S	Oral	400 Milligram Daily;		Not Reported
	Metoclopramide			S	Other	Route Of Administration : Intravenous And Oral		Not Reported
	Ceftriaxone			C	Intravenous (not			Not Reported

		otherwise specified)		
Cefepime	C	Intravenous (not otherwise specified)		Not Reported
Rocuronium	C	Intravenous (not otherwise specified)		Not Reported
Rocuronium	C	Intravenous (not otherwise specified)		Not Reported
Midazolam	C	Intravenous (not otherwise specified)		Not Reported
Propofol	C	Intravenous (not otherwise specified)		Not Reported
Propofol	C	Intravenous (not otherwise specified)		Not Reported
Fentanyl	C	Intravenous (not otherwise specified)		Not Reported
Noradrenaline	C	Intravenous (not otherwise specified)		Not Reported
Furosemide	C	Intravenous (not otherwise specified)		Not Reported
Hydrochlorothiazide	C	Oral		Not Reported
Pravastatine	C	Oral	40 Milligram Daily;	Not Reported
Acetylsalicylic Acid	C	Other	100 Milligram Daily; Route Of Administration: Oral Or Intravenous	Not Reported
Metoprolol	C	Oral	50 Milligram Daily;	Not Reported
Torasemide	C	Oral		Not Reported
Ezetimibe	C	Oral	10 Milligram Daily;	Not Reported
Allopurinol	C	Oral	300 Milligram Daily;	Not Reported
Paracetamol	C	Oral	500 Milligram Daily;	Not Reported
Insuline	C			Not Reported
Clexane	C	Subcutaneous		Not Reported
Duphalac	C			Not Reported
Phosphore Phoscap	C	Oral		Not Reported

	Supradyne Energy	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822465	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02402		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Gestational Hypertension; Nephritis; Treatment Noncompliance	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Novel Labs
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lovenox [Enoxaparin Sodium]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk (Tapering Dose)		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822616	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130913			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Arava			S		Unk		Sanofi
	Methotrexate			S	Oral	1 Df, Qw		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S	Oral	1 G, Qow		Not Reported
	Prednisone			S		10 Mg, Qd		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mirtazapine			C		40 Mg, Qd		Not Reported
	Citalopram Hydrochloride			C		40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822635	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3418091-00		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax Avium			S	Oral	Zitromax Avium 600 Mg Compresse Rivest		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822767	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-248011		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
	Symbicort Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Po...			S	Respiratory (inhalation)	2 Dosage Form, Tid		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822860	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889961		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use;	Rituxan			S	Intravenous (not otherwise specified)	For 8 Months		Not Reported
	Actemra			S	Intravenous (not			Not Reported

Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Unknown	For 7 Months	Not Reported
	Humira	S	Subcutaneous	For 3 To 4 Months	Not Reported
	Leflunomide	S	Unknown	For 5 Months	Not Reported
	Methotrexate Sodium	S	Subcutaneous	For 7 Years	Not Reported
	Orencia	S	Unknown	For 7 Months	Not Reported
	Orencia	S	Subcutaneous	For 7 Months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	For 4 Years	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Every 2 Weeks (For 6 Months)	Not Reported
	Xeljanz	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate	C	Oral		Not Reported
	Arava	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822875	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131129			Female	CAN

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Arava	S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Sanofi
	Methotrexate	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822876	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131104		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Hepatitis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823051	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Arava			S	Oral	20 Mg, 1 Every 1 Day		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg 2 Every 2 Days		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Methotrexate	C		25 Mg, Qw	Not Reported
	Meloxicam	C			Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Celebrex	C	Oral	200 Mg, Qd	Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823052	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA131308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Arava			S	Unknown	20 Mg		Sanofi
	Boric Acid			S	Unknown	Unk		Not Reported
	Benzalkonium Chloride			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Phenylephrine Hydrochloride			S	Unknown	Unk		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Qd		Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Disodium Edetate	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	40 Mg, Qw		Not Reported
Gold	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Sodium Borate	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Unknown	10 Mg, Biw		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Biw		Not Reported
Tofacitinib Citrate	S	Subcutaneous	5 Mg, Biw		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Ibuprofen	C	Oral	400 Mg		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Celebrex	C	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823059	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131297			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823101	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599694		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	126.0 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	17.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Gold			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C				Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Tocilizumab			C	Unknown			Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823332	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247053			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Bronchopulmonary Dysplasia; Failure To Thrive; Foetal Exposure During Pregnancy; Infantile Apnoea; Low	Prednisone			S	Unknown	Unk		Sun
	Aspirin			S	Unknown	Unk		Sun
	Insulin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Birth Weight Baby; Postnatal Growth Restriction; Premature Baby; Pulmonary Hypertension; Retinopathy Of Prematurity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823333	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603909			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased;	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Neurontin			C	Oral			Not Reported
	Gravol			C	Unknown			Not Reported

Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Acuity Reduced; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823551	NON-EXPEDITED			US-PFIZER INC-2020203536		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Swelling	Xeljanz Xr			S		11 Mg		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823651	NON-EXPEDITED			US-MYLANLABS-2020M1046393			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Dyspnoea; Feeling Abnormal; Malaise; Product Packaging Issue; Sensation Of Foreign Body	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	Unk		Mylan
	Hydroxychloroquine Sulfate Tablets, Usp			S				Mylan
	Carvedilol Tablets, Usp			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823953	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-17351			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Unknown	Unknown	Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824015	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247852		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Sun

	Prednisone			S	Unknown	Unk				Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824306	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602237		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Glumetza			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Altace			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	D-Alpha Tocopherol			C	Unknown			Not Reported

Ergocalciferol	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824360	EXPEDITED (15-DAY)		DE, OT	DE-PFIZER INC-2020206049		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day		Not Reported
	Tazobac			C				Not Reported
	Tazobac			C				Not Reported
	Atorvastatin			C				Not Reported
	Meropenem			C				Not Reported
	Apixaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824544	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2598810		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	9999		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Topicorten	S	Cutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824615	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600446		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hepatic Enzyme Increased; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Nortriptyline	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown	Tablet (Extended-Release)	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Acetaminophen	C			Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C			Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	Cholecalciferol	C			Not Reported
	D-Alpha Tocopheryl Acetate	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Lomotil [Loperamide Hydrochloride]	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Loperamide Hydrochloride	C	Unknown		Not Reported
	Nasonex	C	Unknown		Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Perphenazine	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Unknown		Not Reported

	Tylenol	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824666	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598916		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S		Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

	Sulfathalidine	S	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Salazopyrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824860	DIRECT					48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Impaired Work Ability; Insomnia; Pain; Product Quality Issue; Product Substitution Issue; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate - Plauenil	Y		S		Quantity:1 Tablet(S);		Zydus Pharm
	Eliquis			C				Not Reported
	Lasix			C				Not Reported
	Telenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825304	NON-EXPEDITED			US-UCBSA-2019010565			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Glucose Increased; Eye Disorder; Migraine; Nausea; Treatment Failure	Cimzia			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S				Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825441	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600041		32 YR	Female	CAN

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

Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Actemra	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Rituximab	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	Therapy Duration: 21.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Citalopram Hydrobromide	C			Not Reported
	Ketoprofen	C	Unknown		Not Reported
	Losec [Omeprazole]	C	Unknown		Not Reported
	Naprosyn [Naproxen]	C	Unknown		Not Reported
	Omeprazole	C			Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825475	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020205699		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Tachycardia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825739	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1239023		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg		Teva
	Morfina (1982a)			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Furosemida			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825755	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain;	Prednisone			S	Unknown			Actavis
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Oral		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquinesulfate]		S	Unknown	400 Ml Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tofacitinib Citrate		S	Unknown		Not Reported
	Hydroxychloroquine Phosphate		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826171	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1240209		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S	Unknown	1200 Milligram Daily;		Teva
	Hydroxychloroquine			S	Unknown	1200 Milligram Daily; 21.9 Mg/Kg/Day		Teva
	Everolimus			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826300	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202005005429			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injury; Off Label Use; Syncope	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Azithromycine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826306	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202005005461			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Total Lung Capacity Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826307	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005455			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Discomfort; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Malaise; Off Label Use; Product Use Issue; Skin Lesion; Swelling; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Leflunomide			S	Unknown	Film-Coated Tablet		Not Reported
	Methotrexate			S	Oral	20 Mg, Q2m		Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Vitamin D 2000			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826524	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200523250		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug	Rivaroxaban			S	Oral	15 Mg, Qd		Janssen

Level Increased; Drug Interaction	Lopinavir		S	Unknown	Unk	Not Reported
	Ritonavir		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826528	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200523246		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction	Rivaroxaban			S	Oral	15 Mg, Qd		Janssen
	Lopinavir			S				Not Reported
	Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826917	EXPEDITED (15-DAY)		OT	NVSC2020GB139840			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dactylitis; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Joint Swelling; Nausea; Paraesthesia; Psoriatic Arthropathy; Rash; Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Cosentyx			S	Oral	300 Mg		Novartis
	Cosentyx			S	Oral	40 Mg		Novartis
	Methotrexate			S	Oral	10 Mg, (10 Mg To 15 Mg)		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	30 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Sulfasalazine			S	Unknown	4 G, Qd		Not Reported
	Sulfasalazine			S	Unknown	3 G, Qd		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	400 Mg		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	1 Ot, Tiw		Not Reported
Humira	S	Subcutaneous	1 Unk, Q4w		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Leflunomide	C	Unknown	20 Mg		Not Reported
Leflunomide	C	Unknown	10 Mg,		Not Reported
Leflunomide	C	Unknown	20 Mg,		Not Reported
Tocilizumab	C	Subcutaneous	162 Mg, Qw		Not Reported
Abatacept	C	Subcutaneous	125 Mg,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826954	EXPEDITED (15-DAY)		OT	NVSC2020CA034842		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; C-Reactive Protein Increased; Decreased Appetite; Drug Ineffective; Dysstasia; Fatigue; Gait Disturbance; General Physical Health Deterioration; Grip Strength Decreased; Hypokalaemia; Nausea; Pain	Methotrexate			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	14223391	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP021500		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Unk, Unk		Apotex

Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	400 G, Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S			Apotex
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported

Sulfasalazine	S			Not Reported
Gold	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Marijuana	C	Unknown	Unk	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	7 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	Unk	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	15428288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189244		62 YR	Male	CAN

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

Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	15834762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2245786		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16691241	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208333		50 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Sleep Disorder; Treatment Noncompliance	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16720233	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217087		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qow		Not Reported
	Leucovorin [Calcium Folinate]			C	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported
	Coversyl [Perindopril Arginine]			C	Unknown	Unk		Not Reported
	Vitamin D [Ergocalciferol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16774890	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-219753			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Ranbaxy

Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril	S	Unknown	5 Milligram	Ranbaxy
	Pregabalin	S	Unknown	100 Milligram, Tid	Sun
	Omeprazole	S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Astrazeneca
	Omeprazole	S	Unknown	20 Mg, Bid	Astrazeneca
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
	Quensyl	S	Unknown	20 Mg Bid	Not Reported
	Eliquis	S	Unknown	2.5 Milligram, Bid	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Milligram	Not Reported
	Spasmolyt	S	Unknown		Not Reported
	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
	Lyrica	S	Unknown	300 Milligram, Daily	Not Reported
	Lyrica	S		1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))	Not Reported
	Eliquis	S	Unknown	2 Dosage Form, Daily	Not Reported
	Apixaban	S	Unknown	2 Df, Qd	Not Reported
	Apixaban	S	Unknown	2.5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16884537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418235		63 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Endocervical	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Ciclosporin	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17081625	NON-EXPEDITED			US-UCBSA-2018055688		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cimzia			S		Unk		Not Reported
	Vitamin D			C				Not Reported

	Hydroxychloroquine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17333490	EXPEDITED (15-DAY)		HO	CA-ROCHE-2529931		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17376781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Leflunomide	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17416777	EXPEDITED (15-DAY)		OT	US-SA-2020SA038806		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17715753	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2020-020591			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17754876	EXPEDITED (15-DAY)		DE, OT	BE-SA-2020SA115641		83 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Product Use Issue; Respiratory Failure; Wrong Technique In Product Usage Process	Kevzara			S	Intravenous (not otherwise specified)	400 Mg		Sanofi
	Kevzara			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	2 Df, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	1 Df, Bid		Sanofi
	Plaquenil			S	Oral	2 Df, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Bid		Sanofi
	Azithromycin			C	Oral	250 Mg, Qd		Not Reported
	Sodium Chloride			C	Subcutaneous	Unk		Not Reported
	Sodium Chloride			C				Not Reported
	Cefuroxime			C		1 Df, Tid		Not Reported
	Clopidogrel Sandoz [Clopidogrel]			C		75 Mg		Not Reported
	Inderal			C		40 Mg, Qd		Not Reported
	Perindopril			C		4 Mg, Qd		Not Reported
	Morphine Hydrochloride			C	Intravenous bolus	2 Mg, Q4h		Not Reported
	Sodium Chloride			C	Intravenous bolus	2 Mg, Q4h		Not Reported
	Dafalgan Forte			C	Oral	Unk Unk, Q6h		Not Reported
	Dafalgan Forte			C				Not Reported
	Dafalgan Forte			C				Not Reported
	Paracetamol B Braun			C	Intravenous drip	3 Df		Not Reported
	Clexane			C	Subcutaneous	60 Mg, Bid		Not Reported
	Simvastatine			C	Oral	1 Df		Not Reported
	Pantomed [Pantoprazole Sodium Sesquihydrate]			C	Oral	1 Df, Qd		Not Reported
	Pantomed [Pantoprazole Sodium Sesquihydrate]			C	Intravenous bolus	1 Df, Bid		Not Reported
	Basaglar			C	Subcutaneous	22 U, Qd		Not Reported
	Basaglar			C	Subcutaneous	18 U, Bid		Not Reported
	Novorapid			C	Subcutaneous	Unk		Not Reported
	Haldol [Haloperidol]			C	Oral	5 Gtt Drops, Qd		Not Reported

Midazolam B Braun	C	Intravenous bolus	5 Mg		Not Reported
Sodium Chloride	C	Intravenous bolus	Unk		Not Reported
Remergon	C	Oral	1 Df, Qd		Not Reported
Tamsulosin	C	Oral	1 Df, Qd		Not Reported
Ciproxin [Ciprofloxacin Hydrochloride]	C		2 Df, Qd		Not Reported
Cymbalta	C	Oral	1 Df		Not Reported
Coversyl [Perindopril Erbumine]	C	Oral	1 Df		Not Reported
Asaflow	C	Oral	1 Df		Not Reported
Contramal	C	Oral	1 Df		Not Reported
Sildenafil Sandoz	C	Oral	0.5 Df		Not Reported
Zocor	C	Oral	1 Df		Not Reported
Mirtazapine	C		15 Mg		Not Reported
Lantus	C		22 Iu		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17758914	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748937		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 16.0 Year(S)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Therapy Duration: 16.0 Year(S)		Not Reported
	Neoral			S	Subcutaneous	Therapy Duration 15 Years		Not Reported

Neoral	S	Oral			Not Reported
Neoral	S	Subcutaneous	Therapy Duration: 16.0 Year(S)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Therapy Duration: 15 Years		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 16.0 Year(S)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 11 Years		Not Reported
Cyclosporine	S	Unknown			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Enbrel	S	Subcutaneous	Therapy Duration: 3.0 Month(S)		Not Reported
Orencia	S	Subcutaneous	Therapy Duration: 10.0 Months		Not Reported
Orencia	S	Subcutaneous	Therapy Duration: 3.0 Month(S)		Not Reported
Leflunomide	S	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826236	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247563		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826324	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607145		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Benzylpenicillin			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826546	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607098		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			C	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826617	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202005005469			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Hypokinesia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Daily Dosage: 200mg/400mg		Concordia

Fluconazole	S	Unknown	Unk		Not Reported
Dobutamine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826772	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005590			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Multiple Organ Dysfunction Syndrome; Off Label Use; Renal Failure	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		400 Mg, Bid (Day 0)		Concordia
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		400 Mg, Bid (Days 1-4)		Concordia
	Tacrolimus			S	Unknown	6 Mg, Bid		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Lopinavir/Ritonavir			S		400 Mg, Bid (For 5 Days)		Not Reported
	Micafungin			S		100 Mg, Qd		Not Reported
	Sulfamethoxazole-Trimethoprim-Ds			S		Unk		Not Reported
	Heparin			S				Not Reported
	Tobramycin			S		Unk		Not Reported
	Mycophenolic Acid			S		360 Mg, Bid		Not Reported
	Linezolid			S		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Vancomycin			C				Not Reported
	Oseltamavir			C		Unk		Not Reported
	Ivig			C	Intravenous (not otherwise specified)	10 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826838	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005793			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Product Use In	Hydroxychloroquine			S		Unk		Concordia

Unapproved Indication	Cyclosporine	C	100 Mg, Bid (Goal Trough 75-100 Ng/Ml)	Not Reported
	Mycophenolate Mofetil	C	250 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826909	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005005611			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Hydroxychloroquine			S	Unknown	Unk, Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827028	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S		Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827186	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605529		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	5.0 Months		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported

Leflunomide	S	Unknown			Not Reported
Mefenamic Acid	S	Unknown			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Methotrexate	S	Oral			Not Reported
Orencia	S	Unknown			Not Reported
Simponi	S	Unknown	6.0 Months		Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Folic Acid	C				Not Reported
Metformin	C	Unknown			Not Reported
Rabeprazole Sodium	C	Oral			Not Reported
Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827300	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602408		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Rheumatoid Arthritis; Synovitis; Treatment Failure	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 20.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Months	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 12.0 Months	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	Therapy Duration: 2.0 Months	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Cetirizine Hydrochloride	C			Not Reported
	Cortisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Paracetamol	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131242			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Pain In Extremity; Rheumatoid Arthritis	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Levothyroxine Sodium			S	Oral	175 Mg, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827363	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131316		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown	20 Mg		Sanofi
	Celecoxib			S	Unknown	200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827568	EXPEDITED (15-DAY)		OT	ES-SA-2020SA135372		64 YR	Male	ESP

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

Hepatitis; Off Label Use	Hydroxychloroquine	S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine	S				Sanofi
	Azithromycin	S	Oral	500 Mg Day		Not Reported
	Enoxaparin Sodium	S	Subcutaneous	60 Mg		Sanofi
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827635	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247555		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Multiple Organ Dysfunction Syndrome	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827768	NON-EXPEDITED			NVSC2020US143358			Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828357	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1051051		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Hydroxyzine Hydrochloride			S	Intravenous (not otherwise specified)	25 Milligram, Q6h		Mylan

	Plaquenil /00072603/	S	Oral	200 Milligram, Bid, 12 Hrs	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828429	EXPEDITED (15-DAY)		LT	ES-ACCORD-183232		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Intrusive Thoughts; Off Label Use; Suicide Attempt	Hydroxychloroquine			S	Oral	200 Mg Every 12 Hours		Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Cortic			C	Intravenous bolus	Bolus Corticosteroids Iv		Not Reported
	Septrin			C	Unknown			Not Reported
	Kaletra			C	Oral			Not Reported
	Acetylcysteine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828519	NON-EXPEDITED			US-PFIZER INC-2020207672			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Nodal Osteoarthritis; Peripheral Swelling	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828583	EXPEDITED (15-DAY)		LT	CA-ROCHE-2606927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported

Methotrexate	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828703	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005364			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Occlusive Disease; Off Label Use; Pollakiuria; Prostatic Disorder; Tooth Loss	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk,Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601838		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Cetirizine Hydrochloride	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605564		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Unknown		Not Reported
Rabeprazole Sodium	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tofacitinib	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829374	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247397		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829521	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2607349		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Not Reported
	Tocilizumab			S				Not Reported
	Ambisome			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400mg/24h		Not Reported
	Hidroxicloroquina Sulfato			S				Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829594	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1051133		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Off Label Use	Lopinavir/Ritonavir Mylan			S	Oral	4 Dosage Form		Mylan
	Plaquenil /00072603/			S	Oral	100 Milligram, Qd		Mylan
	Calcidose /07357001/			C		Unk		Mylan
	Piperacilline/Tazobactam			C		Unk		Mylan
	Doliprane			C		Unk		Mylan
	Rocephine			C		Unk		Mylan
	Sodium Bicarbonate			C		Unk		Mylan
	Furosemide			C		Unk		Mylan
	Amlodipine			C		Unk		Mylan
	Diffu K			C		Unk		Mylan
	Renvela			C		Unk		Mylan
	Calciparine			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829602	EXPEDITED (15-DAY)		CA, OT	FR-MYLANLABS-2020M1051130			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Achromotrichia Congenital; Foetal Exposure During Pregnancy	Parlodel			S	Transplacental	20 Milligram, Qd		Mylan
	Hydrocortisone Roussel /00028601/			S	Transplacental	100 Milligram, Qd		Mylan
	Zithromax			S	Transplacental	250 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Transplacental	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829606	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1051120		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Qd (500 Mg Dia)		Not Reported
	Enoxaparin			S	Subcutaneous	80 Milligram, Bid (80 Mg Cada 12h)		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram, Qd (600 Mg)		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Milligram, Qd (400 Mg Dia)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829680	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204768		60 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, Daily ((Given In 2 Divided Doses Every 12 Hours)		Not Reported
	Reuquinol			S		400 Mg, Daily (Given In 2 Divided Doses Every 12 Hours)		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, 2x/Day		Not Reported
	Oseltamivir			C	Oral	75 Mg, 2x/Day		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	2.25 G, 3x/Day (Every 8 Hours)		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 4x/Day (Every 6hours)		Not Reported
	Vancomycin Hydrochloride			C	Intravenous (not otherwise specified)	1 G, 2x/Day (Every 12hours)		Not Reported
	Vancomycin Hydrochloride			C	Intravenous (not	1 G, 1x/Day		Not Reported

		otherwise specified)		
Dobutamine	C		Unk	Not Reported
Sodium Bicarbonate	C		Unk	Not Reported
Cis [Cisatracurium Besilate]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Sodium Chloride	C		Unk	Not Reported
Dopacris	C	Intravenous (not otherwise specified)	250 Mg, As Needed	Not Reported
Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
Nexium Mups [Esomeprazole Magnesium]	C		20 Mg, 1x/Day	Not Reported
Lipless	C		Unk	Not Reported
Hydrochlorothiazide	C		Unk	Not Reported
Trezor [Rosuvastatin Calcium]	C		Unk	Not Reported
Metformin	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Tamiram	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829735	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Heart Rate Increased; Hypertension; Nervousness; Panic Attack	Hydroxychloroquine			S				Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829746	DIRECT		DS, OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Gingival Erosion; Tooth Disorder; Tooth Fracture	Orencia 125 Mgs	Y		S	Subcutaneous	Quantity:1 Injection(S);Other Frequency:Once A Week;		Unknown
	Hydroxychloroquine	Y		S	Oral	Quantity:1 Capsule(S);		Prasco
	Morphine 30mg			C				Not Reported
	Oxycodone			C				Not Reported
	Iron Tablets Tablet			C				Not Reported
	Spiriva Respimat 2.5mg			C				Not Reported
	Cetirizine 10mg			C				Not Reported
	Topiramate 100mg			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Lisinopril 5mg			C				Not Reported
	Folic Acid 1mg			C				Not Reported
	Prednisone 4mgs			C				Not Reported
	Calcium 600mgs			C				Not Reported
	Vitamin A			C				Not Reported
	Vitamin D3			C				Not Reported
	Vitamin B 12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829863	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051271			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Symbicort			S	Respiratory (inhalation)	2-2-2		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg Dia		Not Reported

	Salbutamol		S	Respiratory (inhalation)	2-2-2 Inh	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829864	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051272			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg Dia		Not Reported
	Dexametasona [Dexamethasone]			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Enoxaparina			S	Subcutaneous	80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829970	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201805-001826			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Tacrolimus Monohydrate			S	Oral	4 Mg, Qd		Not Reported
	Prednisolone			C		Unk		Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Aspartate Comps			C		Unk		Not Reported
	Aspartate Comps			C				Not Reported

	Takepron	C	Unk	Not Reported
	Bayaspirin	C	Unk	Not Reported
	Warfarin	C	Unk	Not Reported
	Avapro	C	Unk	Not Reported
	Metgluco	C	Unk	Not Reported
	Myslee	C	Unk	Not Reported
	Hyalein Eye Drops	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830033	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005516			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Lupus Nephritis; Off Label Use; Proteinuria; Treatment Noncompliance	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Lovenox			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830175	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1052059		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Tachycardia	Hydroxychloroquine			S	Oral	Approximately 10-11 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830229	EXPEDITED (15-DAY)		OT	NVSC2020CA143801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Drug Ineffective; Panniculitis	Colchicine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gen-Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830468	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000434			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported

	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil /00072603/	S	Oral	400 Mg, Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Arthrotec	S	Intracardiac	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830774	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200525219		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Necrosis; Skin Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830784	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526261		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830922	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1051633		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		500 Milligram, Qd		Not Reported
	Kaletra			S		1 Dosage Form, Bid		Mylan
	Interferon Beta			S		250 Milligram, Q2d		Mylan
	Hidroxicloroquina /00072601/			S		200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	18251897	DIRECT		DE, HO			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Torsade De Pointes	Hydroxychloroquine			S		Other Dose:400mg-200mg;	1 DAY	Not Reported
	Azithromycin			S		Other Dose:500mg-250mg;	2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	18251909	DIRECT		HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Use Issue	Hydroxychloroquine			S	Oral	Other Dose:400/200mg;	4 DAY	Not Reported
	Azithromycin			S	Oral	Other Dose:500mg/250;	4 DAY	Not Reported
	Tocilizumab Intravenous Solution			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	18251932	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Azithromycin			S	Intravenous (not otherwise specified)	Other Route:Iv	4 DAY	Not Reported
	Hydroxychloroquine			S	Oral	Dose: 400mg Bid X 1 Day Then 200 Mg Bid For 3 Days	3 DAY	Not Reported
	Zinc Sulfate			S	Oral		2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	10657398	EXPEDITED (15-DAY)		DS	FR-ASTRAZENECA-2014SE95951		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Inexium			S	Oral			Astrazeneca
	Fosamax			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Lexomil Roche			S	Oral			Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Avodart			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Forlax			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Skenan			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Salazopyrine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	13111870	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1717236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Every Week		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rho(D) Immune Globulin			S	Unknown			Not Reported
	Humira			S	Subcutaneous	4 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Subcutaneous			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Phenylephrine Hcl			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Tofacitinib Citrate	S	Subcutaneous			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Methotrexate Sodium	S	Oral	Qwk		Not Reported
Methotrexate Sodium	S	Subcutaneous			Not Reported
Xeljanz	C	Oral			Not Reported
Ibuprofen	C	Oral			Not Reported
Celebrex	C	Oral			Not Reported
Lipitor [Atorvastatin Calcium]	C	Oral			Not Reported
Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	16695071	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079550			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Apixaban			S	Unknown	2.5 Milligram, Bid		Bristol Myers Squibb
	Apixaban			S	Unknown	2 Dosage Form, Qd		Bristol Myers Squibb
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	100 Milligram, Tid		Not Reported
	Quensyl			S	Unknown	40 Mg, Bid (80mg/Day)		Not Reported
	Quensyl			S	Unknown	20 Milligram, Bid		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Spasmolyt			S	Unknown	30 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form		Not Reported

Omeprazole	S	Oral	1 Dosage Form, Bid	Not Reported
Omeprazole	S	Oral	20 Milligram	Not Reported
Ramipril	S	Oral	1 Dosage Form, Bid	Not Reported
Ramipril	S	Unknown	5 Milligram, Qd	Not Reported
Sildenafil Citrate	S	Unknown	60 Milligram, Daily Dose	Not Reported
Pregabalin	S	Unknown	100 Milligram, Tid	Not Reported
Pregabalin	S	Unknown	1 Dosage Form	Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
Ambrisentan	S	Oral	1 Dosage Form, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17024269	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-GSH201908-001839			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Hydroxychloroquine			S	Unknown	20 Mg, Bid (40 Mg/Day)		Concordia
	Hydroxychloroquine			S	Unknown	40 Mg, Bid (80mg/Day)		Concordia
	Ramipril			S	Oral	1 Dosage Form, Bid, (1 - 0 - 1)		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Lyrica			S	Unknown	1 Dosage Form, Tid		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Bid (1-0-1)		Not Reported
	Omeprazole			S	Oral	20 Mg, Bid		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Volibris			S	Unknown	Unk		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported

	Spasmolyt	S	Unknown	1 Dosage Form, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Apixaban	S	Unknown	2.5 Mg, Bid	Not Reported
	Apixaban	S	Unknown	2 Dosage Form, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw, Solution For Injection In Pre-Filled Syringe	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported
	Ambrisentan	S	Oral	30 Mg, Qd	Not Reported
	Ambrisentan	S	Oral	1 Dosage Form, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17088021	NON-EXPEDITED			US-UCBSA-2018027063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cimzia			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17090199	NON-EXPEDITED			US-UCBSA-2018021530			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Cimzia			S		Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Dose		Not Reported

	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17104636	NON-EXPEDITED			US-UCBSA-2017051005			Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17104656	NON-EXPEDITED			US-UCBSA-2018003810		71 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17208175	NON-EXPEDITED			US-UCBSA-2017031305			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic	Cimzia			S		Unk		Not Reported

Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall; Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy; Synovitis; Type V Hyperlipidaemia	Cetirizine Hydrochloride	S		Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S			Not Reported
	Prolia	S		Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Tofacitinib Citrate	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Humira	S		40 Mg, Weekly (Qw)	Not Reported
	Humira	S			Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Arava	S	Oral	20 Mg Daily	Not Reported
	Aranesp	C			Not Reported
	Oxycodone	C			Not Reported
	Abilify	C		Unk	Not Reported
	Advair	C			Not Reported
	Atenolol	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Crestor	C			Not Reported
	Cytomel	C			Not Reported
	Dorzolamide Hcl	C		Unk	Not Reported
	Duloxetine Hydrochloride	C		Unk	Not Reported
	Duoneb	C			Not Reported
	Famotidine	C			Not Reported
	Finasteride	C			Not Reported
	Furosemide	C			Not Reported
	Gabapentin	C			Not Reported
	Leflunomide	C			Not Reported
	Lovaza	C			Not Reported
	Medrol	C			Not Reported
	Myrbetriq	C		Unk	Not Reported
	Nexium	C			Not Reported
	Fish Oil W/Tocopherol	C			Not Reported
	Oxycodone Hcl	C			Not Reported
	Prochlorperazine Maleate	C			Not Reported

Relpax	C	Not Reported
Singulair	C	Not Reported
Soma	C	Not Reported
Sulfazine Ec	C	Not Reported
Synthroid	C	Not Reported
Tamsulosin Hcl	C	Not Reported
Topamax	C	Not Reported
Topiramate	C	Not Reported
Triamterene/Hctz	C	Not Reported
Voltaren	C	Not Reported
Xalatan	C	Not Reported
Cymbalta	C	Not Reported
Vicodin	C	Not Reported
Vicodin	C	Not Reported
Klonopin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17259883	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17285802	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523752		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17288398	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA013858		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Methotrexate			S	Oral	Qw (1 Every 1 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17290629	EXPEDITED (15-DAY)		DE	CA-ROCHE-2528043		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Prednisone Acetate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17305038	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Finger Deformity; Foot Deformity; Hand Deformity; Hepatic Failure; Hypersensitivity; Infection; Knee Arthroplasty; Ocular Icterus; Osteoarthritis; Pain; Pancreatitis; Upper Limb Fracture; Wrist	Arava			S		Unk		Sanofi
	Celecoxib			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported

Deformity	Methotrexate		C	Subcutaneous	5 Mg, Qw	Not Reported
	Xeljanz		C		5 Mg, Qod	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17307242	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Synovitis; Treatment Failure	Leflunomide			S	Unknown	Unk, Stop Date-??-Oct-2009		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17307937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Unknown	17.5 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	162 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituxan			S	Unknown			Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17309844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17519910	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07738		61 YR	Female	CAN

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

Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept	S	Subcutaneous	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown Single Use Pre-Filled Syringe, Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17614242	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202003002062			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthropathy; Calculus Bladder; Cholecystectomy;	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd Coated Tablet		Concordia

Decreased Immune Responsiveness; Emotional Disorder; Gait Disturbance; Herpes Virus Infection; Herpes Zoster; Off Label Use	Hydroxychloroquine		S	Oral	Coated Tablet1 Dosage Form, Qd	Concordia
	Aradois		C		50 Mg	Not Reported
	Influenza		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17678136	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202004002834			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17769484	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2020M1046097			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17806672	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517490		41 YR	Female	CAN

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

C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Anakinra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17812673	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517494		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17812678	EXPEDITED (15-DAY)		DS, HO	CA-JNJFOC-20200517499		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Joint Swelling; Nausea; Platelet Count Increased; Vitamin D Decreased; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Betahistine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Vitamin C /00008001/			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17820785	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2020202410		40 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported
	Methylprednisolone			C		40-80 Mg, Daily		Not Reported
	Acetaminophen			C		1.2-1.8 G, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832244	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastroenteritis; Hepatitis; Nausea	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Enbrel			C	Unknown	50 Mg, Weekly		Not Reported
	Humira			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832458	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603672		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Gravol			C				Not Reported
	Neurontin			C				Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832947	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247719		25 YR	Female	USA

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

Acute Kidney Injury; Exposure During Pregnancy; Foetal Death; Foetal Growth Restriction; Pre-Eclampsia	Hydroxychloroquine		S	Unknown	Unk	Sun
	Methyldopa		S	Unknown	Unk	Sun
	Nifedipine		S	Unknown	Unk	Sun
	Prednisone		S	Unknown	Unk	Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833269	EXPEDITED (15-DAY)		OT	IL-TEVA-2020-IL-1242016		43 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Drug Ineffective; Gastrointestinal Disorder; Retinal Injury	Methotrexate			S	Unknown	Up To Dose		Barr
	Hydroxychloroquine			S	Unknown			Teva
	Belimumab			S	Unknown			Not Reported
	Triamcinolone			S	Intradermal			Not Reported
	Prednisone			C	Unknown			Not Reported
	Azathioprine			C	Unknown	Up To Dose		Not Reported
	Warfarin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833476	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006533			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Kineret	S	Subcutaneous	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S		Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Anakinra	S	Unknown	100 Mg, Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Desoximetasone	C		Unk		Not Reported
Methotrexate	C		Unk		Not Reported
Prednisone	C				Not Reported
Cortisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833488	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601407		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty;	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365		Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Folic			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 11.0	Not Reported

			Years	
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Months	Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 365	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Subcutaneous		Not Reported
Sulfathalidine	S			Not Reported
Topicort [Desoximetasone]	S	Oral		Not Reported
Topicort [Desoximetasone]	S	Unknown		Not Reported
Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported

	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Salazopyrin	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605476			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833562	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605159		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cetirizine			C				Not Reported
	Cranberry [Vaccinium Spp.]			C	Unknown			Not Reported

	Acetylsalicylic Acid	C	Unknown		Not Reported
	Olopatadine	C			Not Reported
	Prednisone	C			Not Reported
	Quinapril Hydrochloride	C			Not Reported
	Sandoz Rabeprazole	C	Unknown		Not Reported
	Singulair	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833589	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005717			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833726	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001640			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisone			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Methyldopa			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833823	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600694		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product	Actemra			S	Unknown	Therapy Duration 6.0 Years		Not Reported

Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Rituximab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Lyrica	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Off Label Use; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Penicillin G Sodium			S	Unknown			Not Reported
	Penicillin V Potassium			S	Unknown			Not Reported
	Rocuronium			S	Unknown			Not Reported

	Rocuronium Bromide	S	Unknown		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833947	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005760			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Arrest; Diarrhoea; Electrocardiogram Qt Prolonged; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834028	EXPEDITED (15-DAY)		DE, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001722			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Prednisone			S	Transplacental	Unk		Not Reported
	Nifedipine			S	Transplacental	Unk		Not Reported
	Methyldopa			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834089	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-248216		26 YR	Female	ESP

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

Coagulopathy	Azithromycin	S	Oral	500 Mg Dia	Sun
	Dexametasona (722a)	S	Intravenous (not otherwise specified)	20 Milligram, Daily	Not Reported
	Enoxaparina (2482a)	S	Subcutaneous	40 Milligram, Daily	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg ; In Total	Not Reported
	Dexketoprofeno (7312a)	S	Intravenous (not otherwise specified)	25 Milligram, Tid	Not Reported
	Hidroxicloroquina (2143a)	S	Oral	400 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834116	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA133267		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	80 Mg, Every 12 Hours		Sanofi
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, 24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834691	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02479		14 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834700	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Hydrocortisone Valerate	C		Not Reported
	Hydromorphone Hydrochloride	C		Not Reported
	Hydroxychloroquine	C		Not Reported
	Lyderm [Fluocinonide]	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Sodium Aurothiomalate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834701	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201612-006568			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Infliximab			S	Oral	300 Mg, Qd		Not Reported
	Pantoloc			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834702	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-005674			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Paracetamol			S	Unknown	325 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Acetaminophen			S	Unknown	Unk Unk, Prn		Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen, Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Codeine Phosphate			C				Not Reported
	Meloxicam			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Synthroid			C				Not Reported
	Celebrex			C		Unk		Not Reported
	Hydromorph			C				Not Reported
	Leflunomide			C		Unk		Not Reported

	Acetaminophen, Codeine Phosphate			C						Not Reported
	Hydromorphone Hcl			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834709	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001198			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	Unk, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	1 Dosage Form, Weekly (50)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Mefenamic Acid			S		400 Mg, Bid		Not Reported
	Mefenamic Acid			S		2 Dosage Form, Qd		Not Reported
	Mefenamic Acid			S		2 Dosage Form, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			C		Unk		Not Reported

	Advil	C	Unknown	400 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834731	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201811-003897			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Pain; Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Etanercept			S	Unknown	15 Mg, Freq: Unk X 1 Weeks		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Infliximab			S	Unknown	200 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605290			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607444		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Apremilast	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Otezla	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Infliximab	C		Not Reported
	Benzylpenicillin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835046	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001115			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	1 Dosage Form, Unk		Not Reported
	Advil			S	Unknown	400 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
	Mefenamic Acid	S		400 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835073	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204798		65 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Fibrin D Dimer Increased; Gastrointestinal Haemorrhage; Haematochezia; Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Product Use Issue	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 2x/Day		Not Reported
	Reuquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Oseltamivir [Oseltamivir Phosphate]			C		Unk Unk, 2x/Day		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported
	Clexane			C	Subcutaneous	80 Mg, 2x/Day		Not Reported
	Amiodarone Hcl			C	Intravenous (not otherwise specified)	900 Mg, As Needed		Not Reported
	Dormire [Midazolam Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, As Needed		Not Reported
	Fentanest [Fentanyl Citrate]			C	Intravenous (not otherwise specified)	2500 Ug, As Needed		Not Reported
	Noradrenaline [Norepinephrine]			C	Intravenous (not otherwise specified)	16 Mg, As Needed		Not Reported
	Lactulona			C	Oropharingeal	20 Ml, 3x/Day		Not Reported
	Lasix [Furosemide]			C	Intravenous (not otherwise specified)	20 Mg, As Needed		Not Reported
	Luftal Max			C	Oropharingeal	40 Drop, 3x/Day		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Oropharingeal	20 Mg, 1x/Day		Not Reported
	Nujol			C	Oropharingeal	20 Ml, 3x/Day		Not Reported

	Zinforo		C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835077	EXPEDITED (15-DAY)		OT	ES-ACCORD-183570		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Pain; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported
	Kaletra			S	Oral	Strength-200/50 Mg		Not Reported
	Omeprazole			C	Oral			Not Reported
	Paracetamol			C	Oral	Strength-1,000 Mg 40 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835078	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-183327		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Furosemide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835140	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020205698		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835384	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020208562		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparin			S	Subcutaneous	80 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606654		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Pain; Peripheral Swelling; Rash; Swelling; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835500	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3420872-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Symptom; Heart Rate Irregular; Malaise; Weight Decreased	Rinvoq			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835715	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-MAPI_00010560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Kineret			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powderfor Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Cellcept			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not	Unknown, Powder For		Not Reported

			otherwise specified)	Solution Intravenous	
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Celebrex	C		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Humira	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835815	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006254			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	325 Mg, Tablet		Not Reported
	Meloxicam			C		Unk		Not Reported
	Methotrexate			C		25 Mg/Ml		Not Reported

	Synthroid	C	Unk		Not Reported
	Tylenol	C			Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Leflunomide	C	Unk		Not Reported
	Celebrex	C	Unk		Not Reported
	Hydromorphone Hcl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17836106	NON-EXPEDITED			US-PFIZER INC-2020207847		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17836374	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000409			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Ventricular Fibrillation	Furosemide			S	Oral	Unk		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Risordan /07346501/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Irbesartan			S	Oral	Unk		Not Reported
	Carvedilol			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837148	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020208538		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Tavanic			S	Oral	1000 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837487	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526760		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	11379748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1620025		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Synovitis; Treatment Failure; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Prednisone	C	Not Reported
	Hydromorph Contin	C	Not Reported
	Dilaudid	C	Not Reported
	Amlodipine	C	Not Reported
	Eletriptan	C	Not Reported
	Cimzia	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	13251082	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895049		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4.0 Month(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Winpred			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	13266498	EXPEDITED (15-DAY)		OT	CA-BAXTER-2017BAX007297		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole Injection, Usp			S	Unknown	Dosage Form: Not Specified		Baxter
	Metronidazole Injection, Usp			S	Intravenous (not otherwise specified)	Dosage Form: Liquid Intravenous		Baxter
	Arava			S	Unknown	Tablet		Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown	Dosage Form: Tablet		Not Reported
	Bisoprolol Fumarate			S	Unknown	Tablet		Not Reported
	Ceclor			S	Unknown	Dosage Form Not Specified		Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral	Dosage Form: Capsules		Not Reported
	Demerol			S	Unknown	Dosage Form Not Specified		Not Reported
	Erythromycin Estolate			S	Unknown	Dosage Form Not Specified		Not Reported
	Erythromycin			S	Unknown	Dosage Form Not Specified		Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S	Unknown	Dosage Form Not Specified		Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Norfloxacin	S	Unknown	Dosage Form Not Specified	Not Reported
	Plaquenil	S	Unknown	Tablet	Not Reported
	Plaquenil	S	Oral	Tablet	Not Reported
	Prednisone	S	Unknown	Dosage Form Not Specified	Not Reported
	Sulfasalazine	S	Unknown	Dosage Form Not Specified	Not Reported
	Erythro Base	S	Unknown	Dosage Form: Tablet	Not Reported
	Methotrexate	S	Unknown	Dosage Form: Not Specified	Not Reported
	Levofloxacin Hemihydrate	S	Unknown		Not Reported
	Cefaclor	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Meperidine	S	Unknown	Dosage Form: Not Specified	Not Reported
	Apo-Leflunomide	S	Unknown	Dosage Form: Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	14549482	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence;	Amitriptyline			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	500 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Spinal Osteoarthritis; Therapeutic Product Effect Incomplete	Folic Acid	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	14815519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Treatment Failure; Weight Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Year(S) Powder For Solution Intravenous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown	Therapy Duration: 9.0 Month(S)		Not Reported
	Gold			S	Unknown			Not Reported

Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Lyrica	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Varicella Zoster Vaccine Live	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	15454776	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190744		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Clonazepam	C	Oral	Not Reported
Desipramine	C	Unknown	Not Reported
Gabapentin	C	Oral	Not Reported
Nitroglycerin	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	15633947	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT156440		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bronchitis; Chills; Cushingoid; Drug Ineffective; Gastrointestinal Disorder; Haematuria; Headache; Hypertransaminasaemia; Lupus Nephritis; Meningitis Cryptococcal; Muscle Atrophy; Muscle Hypertrophy; Nausea; Off Label Use; Pneumonia; Proteinuria; Pyrexia	Hydroxychloroquine			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	1 G, Qd		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Prednisone			S	Oral	1 Mg/Kg, Qd		Not Reported
	Prednisone			S				Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	350 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	375 Mg/M2, Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Cyclophosphamide			S	Oral	1 Mg/Kg, Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Unk, 1x Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	15734887	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1091973			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Betamethasone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16257921	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039626		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Anakinra			S	Unknown	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16697274	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019344315			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	1 Df, Bid (1 - 0 - 1)		Pfizer
	Ramipril			S	Unknown	5 Mg, Qd		Pfizer
	Apixaban			S	Unknown	2.5 Mg, Bid		Pfizer
	Apixaban			S	Unknown	2 Df, Qd		Pfizer
	Lyrica			S	Unknown	100 Mg, Tid		Pfizer
	Lyrica			S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))		Pfizer
	Pregabalin			S	Unknown	100 Mg, Tid		Pfizer
	Pregabalin			S	Unknown	1 Df, 3x/Day		Pfizer
	Omeprazole			S	Oral	1 Df, Bid (1 - 0 - 1)		Pfizer
	Omeprazole			S	Oral	20 Mg, Bid (40mg/Day)		Pfizer
	Sildenafil Citrate			S	Unknown	60 Mg, Qd		Pfizer
	Quensyl			S	Unknown	40 Mg, Bid (80mg/Day)		Not Reported
	Quensyl			S	Unknown	20 Mg, Bid (40 Mg/Day)		Not Reported
	Volibris			S	Oral	30 Mg, Qd		Not Reported
	Volibris			S	Oral	1 Df, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Mg, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw (Solution For Injection In Pre-Filled Syringe)		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Ambrisentan			S	Unknown	30 Mg, Qd		Not Reported

	Ambrisentan	S	Oral	1 Df, Qd		Not Reported
	Ambrisentan	S		Unk		Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd		Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd		Not Reported
	Ambrisentan	S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16927061	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-096726		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Drug Intolerance; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Irritable Bowel Syndrome; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Lyrica			S	Unknown	150 Milligram		Not Reported
	Sulfasalazin			S	Unknown	1000 Milligram, Bid		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	3000 Milligram, Qd		Not Reported
	Esomeprazole			C	Unknown	40 Milligram, Qd		Not Reported
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported
	Bimatoprost			C	Ophthalmic	Unk Unk, Qd		Not Reported

Pseudoephedrine Hydrochloride	C	Unknown	10 Milligram, Qd		Not Reported
Trazodone	C	Unknown	200 Milligram, Qd		Not Reported
Valsartan	C	Unknown	Unk, Qd		Not Reported
Wellbutrin	C	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16931807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Mobicox			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17245909	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512661		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered;	Actemra			S	Unknown	1.0 Dosage Forms		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S				Not Reported

Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pneumonia; Product Dose Omission; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Baclofen	C	Unknown		Not Reported
	Baclofen	C			Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	1.0 Dosage Forms	Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Levaquin	C	Unknown		Not Reported
	Levaquin	C			Not Reported
	Morphine	C	Unknown		Not Reported
	Zingiber Officinale	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17281970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17299293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525016		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Depomedrol			C	Other			Not Reported

Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Depomedrol	C	Other	Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17376739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533781		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17390927	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540924			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17391235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536677		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Codeine	S			Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 9.0 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 15.0 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Adalimumab	C	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Prednisone	C	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17399182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17464240	EXPEDITED (15-DAY)		HO	CA-ROCHE-2553935			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17472233	EXPEDITED (15-DAY)		HO	CA-ROCHE-2556500		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	6.0 Dosage Forms		Not Reported
	Tacrolimus			S	Unknown	5.0 Dosage Forms		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17614339	EXPEDITED (15-DAY)		DS	CA-ROCHE-2572169		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Sulfate] Simponi		S	Subcutaneous	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17722293	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1227376		74 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use; Sinus Bradycardia	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Stilnox 10 Mg Compresse Rivestite Con Film			C	Oral	10 Mg		Not Reported
	Clexane T			C	Subcutaneous	8000 Ku		Not Reported
	Lansoprazolo Teva Italia 30 Mg Capsule Rigide Gastroresistenti			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17722977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589713			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not			Not Reported

			otherwise specified)		
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17729388	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437131			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17763565	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231867		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Off Label Use; Rash Pustular	Azitromicina Teva Italia (Azithromycin)			S	Oral	500 Mg		Not Reported
	Darunavir			S	Oral	800 Mg		Teva
	Ritonavir Sandoz			S	Oral	100 Mg		Not Reported

Norvasc 5 Mg Compresse	S	Oral	10 Mg		Not Reported
Clexane T	S	Subcutaneous	6000 Ku		Not Reported
Plaquenil	S	Oral	400 Mg		Not Reported
Eutirox	C				Not Reported
Folifill	C				Not Reported
Ceftriaxone Mylan Generics 2000 Mg Polvere Per Soluzione Per Infusione	C	Oral	1 Df		Not Reported
Lasix Fiale	C				Not Reported
Urbason Solubile	C	Intravenous (not otherwise specified)	1 Df		Not Reported
Omeprazole	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17794557	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-024373		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Ventricular Fibrillation	Carvedilol			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Irbesartan Eg			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	Unk		Not Reported
	Azithromycin Pfizer			S	Oral	250 Milligram, Once A Day		Not Reported
	Risordan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17806674	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen

Remicade	S	Intravenous (not otherwise specified)	Janssen
Remicade	S	Intravenous (not otherwise specified)	Janssen
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported

	Methotrexate	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17815304	EXPEDITED (15-DAY)		DE, HO	GR-BIOVITRUM-2020GR2165		51 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Shock	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Teicoplanin			S				Not Reported
	Hydrocortisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17815320	EXPEDITED (15-DAY)		DE, HO, OT	GR-BIOVITRUM-2020GR2200		74 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatomegaly; Hypoxia; Inflammatory Marker Increased; Off Label Use; Pyrexia; Shock; Splenomegaly	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Teicoplanin			S				Not Reported
	Hydrocortisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17815343	EXPEDITED (15-DAY)		DE, OT	GR-BIOVITRUM-2020GR2202		84 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anuria; Off Label Use; Shock; Splenomegaly	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Teicoplanin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17816644	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17824697	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600447		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess;	Rituxan			S	Intravenous (not			Not Reported

Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia;	Ceftazidime	S	otherwise specified) Unknown	Not Reported
	Furosemide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Piperacillin/Tazobactam	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Vancomycin Hydrochloride	S	Unknown	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Actonel	C	Unknown	Not Reported
	Apo Amlo	C		Not Reported
	Apo-K	C		Not Reported
	Diphenhydramine Hydrochloride	C	Oral	Not Reported
	Epoetin Alfa	C		Not Reported
	Escitalopram	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C		Not Reported
	Januvia	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Metoprolol	C		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Slow-K	C		Not Reported
	Tylenol	C		Not Reported

Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Ventolin [Salbutamol Sulfate]	C	Not Reported
	Humalog	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17825815	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204791		72 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Pyrexia	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Clexane			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Euthyrox			C	Oral	37.5 Mg, 1x/Day		Not Reported
	Lorazepam			C	Oral	2 Mg, 1x/Day		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Oral	20 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Novalgina			C	Intravenous (not otherwise specified)	1 G, Every 6 Hours As Needed		Not Reported
	Meclin			C	Oral	50 Mg, 2x/Day		Not Reported
	Puran T4			C		37.5 Ug, 1x/Day		Not Reported
	Domperidone			C		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17825820	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2020204785		62 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Electrocardiogram Qt	Zitromax			S	Intravenous (not	500 Mg, 1x/Day		Pfizer

Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication; Pyrexia			otherwise specified)		
	Reuquinol	S	Oral	400 Mg, 2x/Day 12/12h	Not Reported
	Reuquinol	S		400 Mg, 1x/Day	Not Reported
	Reuquinol	S		200 Mg, 1x/Day	Not Reported
	Atorvastatin Calcium	C		10 Mg, 1x/Day	Not Reported
	Oseltamivir	C	Oral	75 Mg, 2x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	400 Mg, 2x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported
	Meronem	C	Intravenous (not otherwise specified)	1 G, 3x/Day 8 / 8h	Not Reported
	Linezolid	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported
	Sodium Bicarbonate	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Bromoprida	C	Intravenous (not otherwise specified)	10 Mg, 3x/Day	Not Reported
	Potassium Chloride	C		Unk	Not Reported
	Sodium Chloride	C		Unk	Not Reported
	Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed (As Physician Criteria)	Not Reported
	Fentanest [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	2500 Ug, As Needed (As Physician Criteria)	Not Reported
	Hemofol	C	Subcutaneous	5000 Iu, 3x/Day	Not Reported
	Hepamax S	C		Unk	Not Reported
	Nexium [Esomeprazole Magnesium]	C		20 Mg, 1x/Day	Not Reported
	Aradois	C		50 Mg, 1x/Day	Not Reported
	Somalgin	C		81 Mg, 1x/Day	Not Reported

	Exodus [Escitalopram Oxalate]	C	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17830178	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1239952		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia	Hidroxicloroquina (2143a)			S	Oral	400 Mg W / 12 Hours Followed By 200 Mg W / 12 Hours. 1 Dosage Forms		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported
	Ceftriaxona (501a)			S	Unknown	Not Specified		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S	Oral	400 Mg C / 12 Drops.2 Dosage Forms		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836705	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602962		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836720	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605662		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836926	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607346		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Inflammation; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily	Rituximab			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837002	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004856			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz			S	Oral	5 Mg, Bid (60/Btl)		Not Reported
	Amitriptyline			S		Unk, Dose Increased Few Months Ago		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837469	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604978		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837474	EXPEDITED (15-DAY)		DS	CA-ROCHE-2608394		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17838561	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-GSH201801-000253			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Eye Burns; Visual Field Defect; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Per Day (1 Df, Every Morning), Film-Coated Tablet		Concordia
	Lanzor			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Coaprovel			C		Unk		Not Reported
	Ventoline			C		Unk		Not Reported
	Rosuvastatine [Rosuvastatin]			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Irbesartan			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Seretide			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17838967	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201806-001903			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Fluid Retention; Hepatic Enzyme Increased; Herpes Zoster; Purulence; Spondylitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Prednisolone			S	Oral	45 Mg, Qd		Not Reported
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported

Prednisolone	S	Oral	45 Mg, Qd	Not Reported
Prednisolone	S	Oral	40 Mg, Qd	Not Reported
Prednisolone	S	Oral	35 Mg, Qd	Not Reported
Prednisolone	S	Oral	30 Mg, Qd	Not Reported
Prednisolone	S	Oral	25 Mg, Qd	Not Reported
Prednisolone	S	Oral	20 Mg, Qd	Not Reported
Prednisolone	S	Oral	17.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	15 Mg, Qd	Not Reported
Prednisolone	S	Oral	12.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	10 Mg, Qd	Not Reported
Prednisolone	S	Oral	9 Mg, Qd	Not Reported
Prednisolone	S	Oral	8 Mg, Qd	Not Reported
Prednisolone	S	Oral	7 Mg, Qd	Not Reported
Prednisolone	S	Oral	6 Mg, Qd	Not Reported
Prednisolone	S	Oral	5 Mg, Qd	Not Reported
Prednisolone	S	Oral	4 Mg, Qd	Not Reported
Prednisolone	S	Oral	3 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Danazol	S	Oral	200 Mg, Qd	Not Reported
Danazol	S	Oral	300 Mg, Qd	Not Reported
Danazol	S	Oral	400 Mg, Qd	Not Reported
Danazol	S	Oral	300 Mg, Qd	Not Reported
Danazol	S	Oral	200 Mg, Qd	Not Reported
Danazol	S	Oral	100 Mg, Qd	Not Reported
Glycyron (Dl-Methionine;Glycine;Glycyrrhizic Acid, Ammonium Salt)	S	Oral	9 Dosage Form, Qd	Not Reported

Samtirel	C	Unk		Not Reported
Samtirel	C			Not Reported
Slow K	C	Unk		Not Reported
Slow K	C			Not Reported
Nifedipine	C	Unk		Not Reported
Halizon	C	Unk		Not Reported
Furosemide	C	Unk		Not Reported
Magmitt	C	Unk		Not Reported
Magmitt	C			Not Reported
Januvia	C	Unk		Not Reported
Januvia	C			Not Reported
Adona [Carbazochrome Sodium Sulfonate]	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17838999	EXPEDITED (15-DAY)		HO	ES-ROCHE-2608114		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Lipitor [Atorvastatin Calcium]	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839109	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605281		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Off Label Use; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2035026		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Weight Decreased	Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Varenicline Tartrate	S	Oral	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
	Esomeprazole Magnesium;Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Valtrex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839180	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605265		70 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839241	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2605496			Female	CAN

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

Arthralgia; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Neutropenia; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Treatment Failure; Urinary Tract Infection; Wheelchair User	Actemra	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	20.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Celebrex	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Tofacitinib	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839441	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608713		39 YR	Female	CAN

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

Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839787	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02477			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Tacrolimus			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839858	EXPEDITED (15-DAY)		DS	CA-ROCHE-2605576		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Actemra			S	Unknown			Not Reported

Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Unknown	Not Reported
	Aleve		C		Not Reported
	Arava		C		Not Reported
	Prednisone		C	Unknown	Not Reported
	Simponi		C	Subcutaneous	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840168	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605008		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605215		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606318		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cardiac Disorder; Contusion; Croup Infectious; Drug Ineffective; Fatigue; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Humalog			C	Unknown			Not Reported
	Sertraline Hydrochloride			C				Not Reported
	Synthroid			C				Not Reported

Hypersensitivity; Hypertension; Hypotension; Immunosuppression; Influenza; Infusion Related Reaction; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pain; Pain In Extremity; Pertussis; Productive Cough; Rash; Stress; Therapeutic Response Decreased; Treatment Failure; Weight Decreased; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840377	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1051907		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Shock	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840422	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608715		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

Respiratory Tract Infection	Actemra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605589		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Back Pain; Drug Ineffective; Infection; Influenza; Pneumonia; Tooth Fracture; Vaccination Site Cellulitis; Vaccination Site Induration	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pneumococcal Vaccine			S	Unknown	For 1 Month		Not Reported
	Andriol			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Eprosartan Mesilate;Hydrochlorothiazide			C				Not Reported
	Estrogel			C	Unknown			Not Reported
	Nifedipine			C				Not Reported
	Prometrium [Progesterone]			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840626	EXPEDITED (15-DAY)		CA, OT	FR-PFIZER INC-2020208534			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Achromotrichia Congenital; Maternal Exposure During Pregnancy	Zithromax			S	Transplacental	250 Mg, 1x/Day		Pfizer
	Hydrocortisone Roussel [Hydrocortisone Acetate]			S	Transplacental	100 Mg, 1x/Day		Not Reported
	Parlodel			S	Transplacental	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Transplacental	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840766	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1051938		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Azithromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840956	EXPEDITED (15-DAY)		DE, OT	BE-ADVANZ PHARMA-202005005958			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840986	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605191		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported

Sepsis; Spinal Deformity;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841249	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605225		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841275	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1240532		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	160 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841284	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1240452		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Pain	Hidroxicloroquina (2143a)			S	Oral	200 Mg		Teva
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	1 Dosage Form		Not Reported
	Omeprazol (2141a)			C	Oral	20 Mg		Not Reported
	Paracetamol 1.000 Mg 40 Comprimidos			C	Oral	1 Gm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605474		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cefalexin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841669	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1051990		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Enoxaparin			S	Subcutaneous	60 Milligram, Qd, 60 Mg		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 397 Days		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 6 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 560		Not Reported
	Orencia			S	Unknown	Therapy Duration: 471 Days		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 10 Years		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 471 Days	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841767	EXPEDITED (15-DAY)		HO	NVSC2020US147932		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	10-11 G		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605509		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842163	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042185			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605453		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Desoximetasone	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842621	EXPEDITED (15-DAY)		LT	CA-ROCHE-2608325		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842639	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604987			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842640	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605519		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842706	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605538		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	5.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous	8.0 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845062	DIRECT	Y	DE			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Hydroxychloroquine			S	Oral			Actavis
	Actemra			S	Intravenous (not otherwise specified)	Other Frequency:X1;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	15317460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172797		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Drug Hypersensitivity; Drug Intolerance; Gait Disturbance; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17023732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459446		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown	Dossage Form : Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dossage Form : Not Specified		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	Dossage Form : Not Specified		Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown	Dossage Form : Not Specified		Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17260308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517545		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported

Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Asa	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17351049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531131		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]			
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17406344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17454837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552651		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Unknown		Not Reported
	Rituximab	S	Subcutaneous		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Azathioprine	C			Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C			Not Reported
	Penicillamine	C			Not Reported
	Prednisone	C			Not Reported
	Actemra	C	Unknown		Not Reported
	Cyclosporine	C			Not Reported
	D-Penicillamine	C			Not Reported
	Phenylbutazone	C			Not Reported
	Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17559399	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03346		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Oral	Unknown		Not Reported

Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown, Solution	Not Reported
Gold	S	Intramuscular	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Unknown	Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
Sulfasalazine	C	Unknown	Unknown	Not Reported
Wellbutrin	C	Unknown	Unknown	Not Reported
Xeljanz	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17675643	EXPEDITED (15-DAY)		DE, OT	ES-HETERO-HET2020ES00415		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Hetero
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk, Qd		Not Reported
	Prednisona			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17710430	EXPEDITED (15-DAY)		DE	IT-TEVA-2020-IT-1226892		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Transaminases Increased	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17763532	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231868		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Off Label Use; Oral Disorder; Rash Pruritic; Rash Pustular; Rash Vesicular; Stevens-Johnson Syndrome	Hydroxychloroquine			S	Oral	400 Mg		Teva
	Symtuza			S	Oral	1 Dosage Forms		Not Reported
	Triumeq			S	Oral	1 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17777966	EXPEDITED (15-DAY)		HO, OT	LV-ROCHE-2599087		12 YR	Female	LVA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pneumonitis; Systemic Lupus Erythematosus; Weight Decreased	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown	For Short Time Period (1-2 Weeks). Stopped Due To Skin Eruptions		Not Reported
	Rituximab			C	Unknown			Not Reported
	Cyclophosphamide			C	Unknown	For Short Time Period (1-2 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17795926	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235484		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Reactine [Cetirizine]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported

	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609352		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842862	EXPEDITED (15-DAY)		OT	NVSC2020IT148686		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Novartis
	Mycophenolate Mofetil			S	Unknown	1 Df, Qd (Unk Unk, Qd)		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg, Qd, Tapering Dose		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Qd, Dose Tapering		Not Reported

	Prednisone	S	Unknown	10 Mg, Qd, Dose Tapering	Not Reported
	Envarsus	S	Unknown	1 Df, Qd (Unk, Qd)	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Immunoglobulin I.V	C	Unknown	Unk	Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk (Pulses)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842917	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment			otherwise specified)			
	Acetaminophen	S	Unknown			Not Reported
	Apo-Acetaminophen	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tylenol	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606173		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843015	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-026288		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843201	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606270		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Condition Aggravated; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal Discomfort; Nasopharyngitis; Nausea; Night Sweats; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Calcium Folinate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Fentanyl	C	Unknown	Not Reported
	Gabapentin	C	Oral	Not Reported
	Metformin	C	Oral	Not Reported
	Hydrochloride;Sitagliptin			
	Oxycodone Hydrochloride	C	Unknown	Not Reported
	Perindopril Erbumine	C	Oral	Not Reported
	Rabeprazole	C	Oral	Not Reported
	Ranitidine	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Sitagliptin	C	Oral	Not Reported
	Synthroid	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Zopiclone	C	Oral	Not Reported
	Zostavax	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606521		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606514		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843240	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609163			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gamastan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606810		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium/Vitamin D3			C				Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605626		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Headache; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea;	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Prescribed Overdose; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Thyroid Neoplasm; Toxicity To Various Agents; Treatment Failure	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Duration :7 Years	Not Reported
	Humira	S	Unknown	Duration :7 Years	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Duration: 13.0 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843333	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling;	Actemra			S	Intravenous (not			Not Reported

Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection			otherwise specified)			
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous	Frequency: Cyclical		Not Reported
	Enbrel	C	Subcutaneous			Not Reported
	Humira	C	Subcutaneous			Not Reported
	Orencia	C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843367	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605541		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Penicillamine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
	Docusate Sodium	C	Oral		Not Reported
	Doxycycline	C	Oral		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Tobramycin	C	Unknown	0.3 Percent	Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843368	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605484		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Inflammation; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain; Pruritus; Rheumatoid Factor Positive; Seronegative Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Urticaria	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606876			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported

Prednisone	C		Not Reported
Simponi	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609657		49 YR	Female	CAN

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

Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Topical	Not Reported
	Cimzia	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843455	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606569			Female	CAN

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

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843464	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606667		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Codeine			C	Unknown					Not Reported
	Leflunomide			C	Unknown					Not Reported
	Meloxicam			C	Unknown					Not Reported
	Methotrexate			C	Unknown					Not Reported
	Synthroid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843469	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608976		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17064085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2469680		56 YR	Female	CAN

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

Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17552505	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown	162 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586473		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Frequency: Every 1 Days		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843674	EXPEDITED (15-DAY)		HO	CA-ROCHE-2608807		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Breast Cancer Stage Iii; Condition	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Aggravated; Depression; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Hand Deformity; Infection; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Off Label Use; Ovarian Cancer; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Unevaluable Event; Urticaria	Cefazolin	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843675	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609334		71 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843730	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3424015-00		53 YR	Female	CAN

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

Blood Test Abnormal; Burns First Degree	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843746	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	11883803	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1687418		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Intentional Product Use Issue; Joint	Naproxen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Every 2 Days		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 731.0 Nos	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C			Not Reported
	Folic Acid	C			Not Reported
	Celebrex	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12330313	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1750335		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2, Therapy Duration: 2 Years Therapy Duration: 12 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg X 2	Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown	Therapy Duration: 10 Months	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Therapy Duration: 20 Years	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 365	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 20 Years	Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 20 Years	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported

Azathioprine	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Etanercept	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Naproxen	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Prednisolone	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12769617	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall;	Rituxan			S	Intravenous (not			Not Reported

Headache; Injury; Nausea; Off Label Use; Treatment Failure; Vomiting			otherwise specified)		
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12838058	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840826		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Solution For Injection In Pre-Filled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Remicade	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12859898	EXPEDITED (15-DAY)		OT	CA-ROCHE-1695809		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration 4 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Therapy Duration: 10.0 Month(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	13854687	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	14633459	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019566		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15461181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	16480475	EXPEDITED (15-DAY)		OT	US-MALLINCKRODT-T201804782			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthralgia; Arthritis; Back Pain; Blood Cholesterol Abnormal; Blood Sodium Increased; Blood Uric Acid Increased; Chest Pain; Depression; Dizziness; Eye Haemorrhage; Fatigue; Gait Disturbance; Headache; Heart Rate Increased; Hyperhidrosis; Hypertension; Hypoaesthesia; Immune System Disorder; Infection; Influenza; Insomnia; Malaise; Memory Impairment; Menorrhagia; Mental Fatigue; Mobility Decreased; Mood Altered; Muscle Spasms; Muscular Weakness; Musculoskeletal Pain; Nausea; Neck Pain; Nervousness; Pain; Pain In Extremity; Pallor; Papilloedema; Poisoning; Polymenorrhoea; Product Dose Omission; Proteinuria; Renal Impairment; Sciatica; Sensitivity To Weather Change; Somnolence; Stress; Systemic Lupus Erythematosus; Vision Blurred; Visual Impairment; Vomiting; Weight Decreased	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Unknown	40 Units/1 Ml		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units / 0.5 Ml, 1 Time Weekly, Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units / 1 Ml, 1 Time Weekly, Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units Once Weekly		Mallinckrodt
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Unk		Not Reported
	Prednisone			C	Unknown	Unk, Every Other Day		Not Reported
	Prednisone			C	Unknown	Unk, Once A Day		Not Reported
	Cellcept			C	Unknown	Unk		Not Reported
	Benlysta			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	16561502	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351627		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17121205	EXPEDITED (15-DAY)		OT	US-UCBSA-2017020170			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Pruritus; Rash; Rheumatoid Arthritis	Cimzia			S		Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Weekly (Qw)		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			C	Oral	3 Mg, Once Daily (Qd)		Not Reported
	Nexium			C	Oral	20 Mg Daily		Not Reported
	Tofacitinib			C	Oral	11 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17183725	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Drug Ineffective; Flank Pain; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased; White Blood Cell Disorder	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Cortisone			C	Intramuscular	Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17245688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512708		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17260299	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous bolus	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17266000	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2516492		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	365		Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	365	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Oral	365.0	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not		Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	365.0	Not Reported
	Sulfasalazine	S	Oral	365.0	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Topicort [Desoximetasone]	S	Cutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S	Cutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Cortisone	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Salazopyrin	C			Not Reported
	Leflunomide	C	Unknown		Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17336937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17370571	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2533713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported

Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17397440	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050946		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S		100 Mg, Unk		Not Reported
	Celebrex			S		200 Milligram		Not Reported
	Celebrex			S				Not Reported
	Celebrex			S		Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	1 Ml, Weekly (Qw)		Not Reported
	Plaquenil			S				Not Reported
	Apo-Prednisone			S		7 Mg, Once Daily (Qd)		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Once Daily (Qd)		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Milligram, Once Daily (Qd); Powder For Solution Intravenous		Not Reported

Simponi	S	Subcutaneous	Solution	Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Hydroxychloroquine	S		300 Milligram, Once Daily (Qd)	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Arava	S			Not Reported
Prednisone	S		7 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Monthly (Qm)	Not Reported
Celecoxib	S		Unk	Not Reported
Celecoxib	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Acetaminophen And Codeine Phosphate	C		Unk	Not Reported
Altace	C		5 Milligram	Not Reported
Altace	C		10 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C		300 Milligram	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Once Daily (Qd)	Not Reported
Atorvastatin Calcium	C		40 Milligram, Once Daily (Qd)	Not Reported
Cipralex [Escitalopram]	C		Unk	Not Reported
Hydromorphone Hcl	C	Oral	30 Milligram, 2x/Day (Bid)	Not Reported
Mupirocin	C	Topical	Unk	Not Reported
Pantoloc [Pantoprazole]	C		20 Milligram, Once Daily	Not Reported

				(Qd)		
	Shark Liver Oil	C		Unk		Not Reported
	Tapentadol Hydrochloride	C		50 Milligram		Not Reported
	Taro-Mupirocin	C	Topical	Unk		Not Reported
	Tramacet	C	Oral			Not Reported
	Tramadol Hydrochloride	C	Oral	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17454584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555257		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

	Acetaminophen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17457814	EXPEDITED (15-DAY)		HO	CA-UCBSA-2020007174		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C		1 Milligram, Weekly (Qw)		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17567657	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022553		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5.0 Milligram 2 Every 1 Days	Not Reported
	Xeljanz	S	Unknown	5.0 Milligram 2 Every 1 Days	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Remicade	C	Intravenous (not otherwise specified)		Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17578950	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Enbrel	S	Unknown	50 Milligram, Qwk		Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	2000 Milligram		Not Reported
Synthroid	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Meloxicam	C	Unknown			Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17601685	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002044			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Burning Sensation; Constipation; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Bid (One In Morning And One In Evening, Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	3 Dosage Form (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Amoxlcillin Trihydrate/Potassium Clavulanate			S	Unknown	Unk		Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Lercan			C		10 Mg		Not Reported

	Quinine			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17648477	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-VALIDUS PHARMACEUTICALS LLC-SK-2020VAL000270			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Metoprolol Tartrate			S	Transplacental	Unk		Validus
	Cefotaxime Sodium			S	Transplacental	Unk		Validus
	Cefotaxime Sodium			S	Transplacental	Unk		Validus
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Cefixime			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Omeprazole			S	Transplacental	Unk		Not Reported
	Magnesium Lactate			S	Transplacental	Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Bisoprolol Fumarate			S	Transplacental	Unk		Not Reported
	Fluconazole			S	Transplacental	Unk		Not Reported
	Hydrocortisone			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Benzylpenicillin Sodium			S	Transplacental	Unk		Not Reported
	Colecalciferol			S	Transplacental	Unk		Not Reported
	Cefazolin Sodium			S	Transplacental	Unk		Not Reported

	Albumin (Human)	S	Transplacental	Unk		Not Reported
	Vitamin B Complex	S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk		Not Reported
	Flebogamma Dif /00025201/	S	Transplacental	Unk		Not Reported
	Privigen	S	Transplacental	Unk		Not Reported
	Privigen	S	Transplacental	Unk		Not Reported
	Bisulepin	S	Transplacental	Unk		Not Reported
	Folic Acid	S	Transplacental	Unk		Not Reported
	Etamsylate	S	Transplacental	Unk		Not Reported
	Nadroparine	S	Transplacental	Unk		Not Reported
	Ornidazole	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17717838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589516			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17767050	EXPEDITED (15-DAY)		HO, LT, OT	JP-FERRINGPH-2020FE02993		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder;	Lutinus			S	Vaginal	300 Mg, Daily		Ferring

Exposure During Pregnancy; Hormone Level Abnormal; Hypogonadism; Infarction; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Vaginal Haemorrhage	Estradiol		S	Transdermal		Not Reported
	Tacrolimus Monohydrate		S	Unknown	4 Mg	Not Reported
	Dydrogesterone		S	Oral	15 Mg, 1 Time Daily	Not Reported
	Prednisolone		S	Unknown	7.5 Mg	Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17769919	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596223			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17770941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591746		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Vaginal	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported

Anakinra	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Codeine	C		Not Reported
Cortisone	C	Intramuscular	Not Reported
Cortisone	C	Oral	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Oral	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Intra-articular	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Oral	Not Reported
Dilaudid	C		Not Reported
Diphenhydramine	C		Not Reported
Dexmethasone	C		Not Reported
Dilaudid	C		Not Reported
Diphenhydramine	C		Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Not Reported
Dyclone	C		Not Reported
Furosemide	C		Not Reported
Hydromorphone	C		Not Reported
Kadian	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C		Not Reported
Lasix [Furosemide]	C		Not Reported
Leflunomide	C		Not Reported
Loperamide	C		Not Reported
Morphine Sulfate	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omnaris	C		Not Reported
Orencia	C		Not Reported
Orphenadrine	C		Not Reported
Orphenadrine Citrate	C		Not Reported

Oxyneo	C		Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Pantoprazole	C		Not Reported
Pantoprazole Sodium Anhydrous	C		Not Reported
Plantago Ovata	C		Not Reported
Restasis	C		Not Reported
Sodium Aurothiomalate	C		Not Reported
Synthroid	C		Not Reported
Triamcinolone Acetonide	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17806211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17816647	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17840976	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1240829		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Forms		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844014	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606464		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Zinc Citrate	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Atorvastatin Calcium	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Digoxin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Furosemide Sodium	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Nifedipine	C	Unknown	Not Reported
	Palafer	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

	Prednisone		C	Unknown	Not Reported
	Synthroid		C	Unknown	Not Reported
	Tocilizumab		C	Unknown	Not Reported
	Toloxin [Digoxin]		C	Unknown	Not Reported
	Trazodone		C	Unknown	Not Reported
	Valsartan		C	Unknown	Not Reported
	Vitamin D3		C	Unknown	Not Reported
	Xarelto		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844059	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609912		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844091	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042281			Female	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia		S	Unknown		Bristol Myers Squibb
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844304	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Inflammation; Interstitial Lung Disease; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Duration: 631.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Duration: 631.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Duration: 631.0 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Duration: 631.0 Days		Not Reported
	Leflunomide			S	Oral	Duration: 631.0 Days		Not Reported
	Leflunomide			S				Not Reported

Methotrexate	S	Unknown	Duration: 631.0 Days		Not Reported
Naproxen	S	Unknown	Duration: 631.0 Days		Not Reported
Naproxen	S	Unknown	Duration: 631.0 Days		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Duration 7 Yaers		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844330	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042253			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Orencia			S	Unknown			Bristol Myers Squibb
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844331	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL		42 YR	Male	FRA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	250 Milligram, Daily		Sun
	Hydroxyzine			S	Intravenous (not otherwise specified)	25 Milligram, Qid		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844526	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606128		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	3.0 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844569	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606231		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure			otherwise specified)	
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

	Alendronate Sodium	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604929		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Victim Of Crime	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844809	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020021835		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Hand Deformity;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Maternal Exposure During Pregnancy; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Methotrexate	S			Not Reported
	Acetaminophen	C			Not Reported
	Amitriptyline	C		10 Milligram, Once Daily (Qd)	Not Reported
	Azithromycin	C			Not Reported
	Domperidone	C		3 Dosage Form	Not Reported
	Esomeprazole Sodium	C		20 Milligram	Not Reported
	Gabapentin	C		400 Milligram, Once Daily (Qd)	Not Reported
	Metonia	C		5 Milligram	Not Reported
	Prednisone	C		8 Milligram, Once Daily (Qd)	Not Reported
	Ranitidine	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844813	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Topical			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844869	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606387		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605361			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Off Label Use; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610701		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845025	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609928			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845029	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609758			Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Rituximab	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609836			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Synovitis	Rituximab			S	Unknown	3.0 Years		Not Reported
	Enbrel			S	Unknown	260.0 Days		Not Reported
	Humira			S	Subcutaneous	346.0 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	9.0 Years		Not Reported
	Methotrexate			S	Unknown	2040.0 Days		Not Reported
	Remicade			S	Unknown	2.0 Years		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	2.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845067	EXPEDITED (15-DAY)		HO	CA-ROCHE-2610757			Male	CAN

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

Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Sulfate]					
Prednisone	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous	Solution For Injection In Pre-Filled Pen		Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845121	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606664		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Gravol			C				Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845122	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020021834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Azathioprine			S		150 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Weekly (Qw)		Not Reported
	Sulfasalazine			C		500 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606067		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Allopurinol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609143		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective For Unapproved Indication; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Treatment Failure; Weight Decreased	Rituximab			S	Intravenous drip			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Varicella-Zoster Immune Globulin			S	Subcutaneous			Not Reported
	Varicella-Zoster Immune Globulin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845263	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported

	Cefazolin	C			Not Reported
	Clindamycin	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Tylenol With Codeine No.3	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845290	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605381		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609611		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611697			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Nodule;	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Treatment Failure	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845521	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02514		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Unknown	Unk		Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	Aspirine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Magnesium			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845639	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607143			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 1460.0 Days		Not Reported
	Azathioprine			S	Oral			Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 187.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Ketoprofen			S	Topical			Not Reported
	Leucovorin Calcium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)			
	Prevnar 13	S	Intramuscular	Therapy Duration: 1.0 Days		Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845687	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242647		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845826	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606204		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845902	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001724			Unknown	USA

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

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose	Hydroxychloroquine		S	Oral	Approximately 10-11 Gram	Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845914	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241289		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hidroxicloroquina			S		200 Mg		Teva
	Azitromicina			S		500 Mg		Not Reported
	Kaletra			S		1 Dosage Form		Not Reported
	Interferon Beta			S		250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845932	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02532			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Bronchopulmonary Dysplasia; Failure To Thrive; Fat Tissue Increased; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Haemangioma; Infantile Apnoea; Postnatal Growth Restriction; Premature Baby; Pulmonary Hypertension; Retinopathy Of Prematurity	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Sildenafil			S	Unknown	1 Milligram/Kilogram, Tid		Lupin
	Prednisone			S	Transplacental	Unk		Not Reported
	Insulin			S	Transplacental	Unk		Not Reported
	Aspirine			S	Transplacental	Unk		Not Reported
	Nifedipine			S	Transplacental	Unk		Not Reported
	Magnesium			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845945	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846128	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1241996		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Cyclophosphamide			S	Unknown	150 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606404		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 8.0 Years		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846172	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-183691		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Hydroxychloroquine			S				Not Reported
	Kaletra			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846261	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242759		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax Plus D Cal			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605494		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Vomiting	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606618			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846438	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1241766		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Piperacilina Tazobactam			S	Intravenous (not otherwise specified)	1 Amp/8h		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846439	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1241777		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Encephalopathy; Pancytopenia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Amoxicilina Clavulanico			S	Intravenous (not otherwise specified)	1 Gr Every 12 Hours X 5 Days Followed By 1gr Every 8 Hours X 6 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846492	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609048		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846572	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020212010		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846772	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241463		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram		Not Reported
	Hidroxicloroquina 200 Mg Comprimido			S		200 Milligram		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846790	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown	2190.0 Days		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846996	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846998	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2020212284			Female	NLD

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

Haemolytic Anaemia	Etanercept	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Methotrexate	S	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847045	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020211935		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Repolarisation Abnormality; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847047	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020212312		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Product Use In Unapproved Indication; Shock	Azithromycin			S	Unknown	Unk		Pfizer
	Methylprednisolone Sodium Succinate			S	Unknown	Unk		Pfizer
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847132	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020211145			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Pain; Rheumatoid Arthritis; Swelling; Therapeutic	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported

Product Effect Decreased	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606599			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606635		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Rituximab			S	Unknown	Therapy Duration:3.0 Years		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 9.0 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 346.0 Days		Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 9.0 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 7.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847469	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606548		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Urethral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847583	EXPEDITED (15-DAY)		OT	US-009507513-2005USA008649			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphocytopenia Neonatal	Celestone Soluspan			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Tacrolimus			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Panniculitis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Colchicine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847672	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606953		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Headache; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847686	NON-EXPEDITED			US-009507513-2006USA000273			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Celestone Soluspan			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Tacrolimus			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847700	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1242689		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Mycophenolate Mofetil			S	Unknown			Teva
	Apo-Azathioprine			S	Unknown	100 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	50 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S				Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847704	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242753		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847787	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042381			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported

	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847848	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540932		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	12309292	EXPEDITED (15-DAY)		HO	CA-ROCHE-1746971			Male	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Synovitis; White Blood Cell Count Decreased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 6 Months	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 5 Months	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 581 Days	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 581 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	12913692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091875		79 YR	Female	CAN

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

Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Intracardiac	8 Milligram/Kilogram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Rituximab;Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Unk	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

Sumatriptan Succinate	C	Unknown	Unk		Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
Amitriptyline	C	Unknown			Not Reported
Sumatriptan	C	Unknown			Not Reported
Tofacitinib	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	13286858	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1899556		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 330.0 Day(S)		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported

Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celebrex	S	Unknown	Not Reported
	Fentanyl Citrate	S	Epidural	Not Reported
	Fentanyl Matrix	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Nortriptyline Hydrochloride	S	Oral	Not Reported
	Nortriptyline Hydrochloride	S		Not Reported
	Nortriptyline Hydrochloride	S	Unknown	Not Reported
	Nortriptyline Hydrochloride	S		Not Reported
	Omega 3 Fish Oils	S	Unknown	Not Reported
	Orencia	S	Vaginal	Not Reported
	Orencia	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Thiamine Hydrochloride	S	Unknown	Not Reported
	Thiamine Hydrochloride	S	Unknown	Not Reported
	Vitamin B-1	S	Unknown	Not Reported
	Xeljanz	S	Endocervical	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C	Unknown	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Nasonex	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Trazodone Hydrochloride	C	Oral	Not Reported
Tylenol	C	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Biotin	C	Unknown	Not Reported
Cholecalciferol	C	Unknown	Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
D-Alpha Tocopheryl Acetate	C	Unknown	Not Reported
Diphenoxylate	C	Unknown	Not Reported
Diphenoxylate	C	Unknown	Not Reported
Docosahexaenoic Acid	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Fergon	C	Unknown	Not Reported
Ferrous Fumarate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported

	Esomeprazole	C	Unknown	Not Reported
	Nicotinamide	C	Unknown	Not Reported
	Perphenazine	C	Oral	Not Reported
	Perphenazine	C	Unknown	Not Reported
	Pyridoxine	C	Unknown	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Not Reported
	Retinol Palmitate	C	Unknown	Not Reported
	Riboflavin	C	Unknown	Not Reported
	Sodium Ascorbate	C	Unknown	Not Reported
	Tecta	C	Unknown	Not Reported
	Thiamine Hydrochloride	C	Unknown	Not Reported
	Thiamine Mononitrate	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Vitamin B12 [Cyanocobalamin]	C		Not Reported
	Vitamin D3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	14206623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025500		36 YR	Female	CAN

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

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	14827888	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2110529		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Month(S)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	6.0 Months		Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duaration: 3months		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

Product Effect Decreased; Vomiting	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone	S	Other			Not Reported
	Adalimumab	S	Subcutaneous	Therapy Duration: 3.0 Months		Not Reported
	Adalimumab	S	Unknown			Not Reported
	Apo-Naproxen	S	Unknown			Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Triamcinolone Hexacetonide	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	14917666	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007162		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Tofacitinib Citrate	S	Oral	5.0 Mg, Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15422962	EXPEDITED (15-DAY)		OT	DE-ROCHE-2186283		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituximab			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Ciclosporin			S	Subcutaneous	Unk		Not Reported

Hydroxychloroquine	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Subcutaneous			Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Oral	Unk		Not Reported
Neoral	S	Oral	Unk		Not Reported
Neoral	S	Subcutaneous	Unk		Not Reported
Leflunomide	S	Unknown			Not Reported
Sulfasalazine	S	Oral			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Xeljanz	C	Oral	5 Mg Bid		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15619727	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555831-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15629381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558926-00		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15978220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Methotrexate	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	C	Unknown	10 Milligram		Not Reported
Cimzia	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	16537770	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063625		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100.0 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Millilitre Per Kilogram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	16884373	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000458			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Drug Ineffective; Dyspepsia; Frustration Tolerance Decreased; Hypersensitivity; Increased Tendency To Bruise; Joint Stiffness; Paraesthesia Oral; Rash	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Alemtuzumab			S	Intravenous drip	12 Mg, Qd		Not Reported
	Tysabri			C				Not Reported
	Copaxone			C				Not Reported
	Betaseron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17281615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518250		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Methylprednisolone	C			Not Reported
	Naprosyn E	C			Not Reported
	Oxycontin	C	Unknown	Tablet (Extended Release)	Not Reported
	Oxyneo	C	Unknown	Tablet (Extended Release)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17486761	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202002001091			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acantholysis; Blister; Dermatitis; Herpes Zoster; Inflammation; Macule; Pain; Pruritus; Skin Plaque; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Oral	100 Mg, Qd, Plaquenil Tablet		Concordia
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	35 Mg, Qd		Not Reported
	Prednisone			S	Unknown	30 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd, Tapering Dose		Not Reported
	Imuran			S	Oral	50 Mg, Qd		Not Reported
	Shingrix			S	Unknown	Unk,To Her Right Deltoid		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Ortho-Novum			C		Unk		Not Reported
	Zyrtec			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17535302	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566151		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Simponi	C	Subcutaneous		Not Reported
Simponi	C			Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17552428	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021329		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17561204	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021856		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive	Orencia			S	Unknown			Bristol Myers Squibb

Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen	S	Unknown	325 Milligram	Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram, 4 Every One Week	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q12h	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous	2000 Milligram	Not Reported
	Leflunomide	S	Unknown	200 Milligram, Qd	Not Reported
	Tylenol	S	Unknown		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, 1 Every 1 Days	Not Reported
	Codeine	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk, Qwk	Not Reported
	Synthroid	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

	Celecoxib		C	Unknown	Unk	Not Reported
	Acetaminophen;Codeine Phosphate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17563694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17741749	EXPEDITED (15-DAY)		OT	CH-SA-2020SA114056			Unknown	CHE

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

Hepatocellular Injury	Plaquenil	S	Oral	In Total	Sanofi
	Amoxicillin Sodium/Potassium Clavulanate	S	Intravenous drip	1.2 G, Qid	Not Reported
	Lopinavir/Ritonavir	S	Oral	400 Mg, Bid	Not Reported
	Lopinavir/Ritonavir	S	Oral	400 Mg, Bid	Not Reported
	Clexane	S	Subcutaneous	40 Mg, Qd	Sanofi
	Clexane	S	Subcutaneous	40 Mg, Bid	Sanofi
	Clexane	S	Subcutaneous	Unk	Sanofi
	Clexane	S	Subcutaneous	40 Mg, Bid	Sanofi
	Paracetamol	S	Intravenous (not otherwise specified)	Max 3x/D ; As Necessary	Not Reported
	Piperacillin/Tazobactam	S	Intravenous drip	4.5 G, Tid	Not Reported
	Azithromycin	S	Oral	500 Mg, Qd	Not Reported
	Ipramol	C		Unk	Not Reported
	Temesta [Lorazepam]	C			Not Reported
	Tavanic	C			Not Reported
	Atracurium	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Dormicum [Midazolam Hydrochloride]	C		Unk	Not Reported
	Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C		Unk	Not Reported
	Antibiotics For Otic And Nasal Use	C		Unk	Not Reported
	Torasemide	C			Not Reported
	Potassium	C			Not Reported
	Benerva	C			Not Reported
	Heparin	C		Unk	Not Reported
	Solu-Medrol	C		Unk	Not Reported
	Novorapid	C		Unk	Not Reported
	Relistor	C		Unk	Not Reported
	Novasource Gi Control	C		Unk	Not Reported
	Ventolin [Salbutamol]	C		Unk, Prn	Not Reported

	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17794311	EXPEDITED (15-DAY)		DE	IT-TEVA-2020-IT-1235086		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema Multiforme; Neutrophilia; Off Label Use; Rash Erythematous	Darunavir			S	Oral	800 Mg		Teva
	Plaquenil			S	Oral	400 Mg		Not Reported
	Ritonavir Sandoz			S	Oral	100 Mg		Not Reported
	Soldesam			C	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported
	Bisoprolol Fumarate			C	Oral	1.25 Mg		Not Reported
	Perindopril			C	Oral	5 Mg		Not Reported
	Atorvastatin			C	Oral	40 Mg		Not Reported
	Cardioaspirin			C		1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17795117	EXPEDITED (15-DAY)		HO, LT, OT	JP-ASCEND THERAPEUTICS US, LLC-2083841		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Hormone Level Abnormal; Hormone Level Abnormal; Hypogonadism; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage; Vaginal	Estrogel			S				Ascend
	Progesterone (Progesterone) (Vaginal Tablet), Unknown			S	Vaginal			Not Reported
	Tacrolimus Monohydrate (Tacrolimus Monohydrate), Unknown			S				Not Reported
	Dydrogesterone (Dydrogesterone), Unknown			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine (Hydroxychloroquine), Unknown			S				Not Reported

Haemorrhage	Estradiol		S	Transdermal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17805102	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202005005322			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Malaise; Pain; Rheumatoid Arthritis; Rheumatoid Factor Quantitative Increased; Therapy Cessation	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Concor			C		Unk		Not Reported
	Libian21			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17813083	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3408479-00		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Interferon Beta 1b			S	Unknown			Not Reported
	Interferon Beta 1b			S	Unknown			Not Reported
	Azitromicina			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Enoxaparina			C	Subcutaneous			Not Reported
	Insulina Novorapid			C	Subcutaneous			Not Reported
	Acetilcisteina			C	Oral			Not Reported
	Omeprazol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17842961	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain;	Alendronate			S	Unknown	Unk		Apotex

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone		S	Unknown	Unk	Not Reported
	Cetirizine		S	Unknown	Unk	Apotex
	Folic Acid		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Apotex
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848291	EXPEDITED (15-DAY)		OT	CO-ABBVIE-19K-036-3214198-00			Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Discomfort; Dizziness; Dry Eye; Dry Mouth; Eye Inflammation; Fibromyalgia; Gastritis; Hernia; Inflammation; Insomnia; Intervertebral Disc Protrusion; Mobility Decreased; Mobility Decreased; Nausea; Oropharyngeal Pain; Pain; Pelvic Floor Dysfunction; Spinal Pain; Tachycardia;	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Deflazacort			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848306	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020021830		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Prednisone			S	Oral	1 Dosage Form, Once Daily (Qd)		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Prednisone			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, 2x/Day (Bid)		Not Reported
	Rituxan			S		1 Gram, 2x/Day (Bid)		Not Reported
	Rituximab			S		1000 Milligram, 2x/Day (Bid)		Not Reported
	Simponi			S		50 Milligram		Not Reported
	Sulfasalazine			S		Unk		Not Reported

	Tofacitinib Citrate	S	5 Milligram, 2x/Day (Bid)		Not Reported
	Xeljanz	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848313	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Methotrexate Sodium			S	Unknown			Pfizer
	Ibuprofen			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848330	EXPEDITED (15-DAY)		HO, OT	TR-IPCA LABORATORIES LIMITED-IPC-2020-TR-001729			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricular Dysfunction; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848351	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242648		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy;	Mycophenolate Mofetil			S	Unknown			Teva

Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848377	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245897		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848423	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042737		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nephrolithiasis; Somnolence; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown	325 Milligram		Not Reported

Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
Enbrel	S	Unknown	40 Milligram, Qwk	Not Reported
Enbrel	S	Unknown	50 Milligram, Qd	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	2000 Milligram	Not Reported
Tylenol	S	Unknown	2000 Milligram	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848440	EXPEDITED (15-DAY)		DS	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001714			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hypotension	Hydroxychloroquine			S	Unknown	800 Milligram		Ipca

Mirabegron	C	Unknown	Unk		Not Reported
Amoxicillin	C	Unknown	Unk		Not Reported
Digoxin	C	Unknown	Unk		Not Reported
Paracetamol	C	Unknown	Unk		Not Reported
Adcal-D3	C	Unknown	Unk		Not Reported
Bisoprolol	C	Unknown	Unk		Not Reported
Omeprazole	C	Unknown	Unk		Not Reported
Dabigatran	C	Unknown	Unk		Not Reported
Alendronic Acid	C	Unknown	Unk		Not Reported
Atorvastatin	C	Unknown	Unk		Not Reported
Gabapentin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848564	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported

Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	100 Milligram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	C	Unknown	70 Milligram, Qwk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, 1 Every 24 Day	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848607	EXPEDITED (15-DAY)		HO	ES-ROCHE-2609953		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Hypofibrinogenaemia	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Dolquine			S	Other	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848793	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015772			Female	CAN

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

Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Live Birth; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Diclofenac	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo Prednison	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S		Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Salazopyrine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606933		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Intentional Product Use Issue; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848987	EXPEDITED (15-DAY)		OT	ES-SA-2020SA138605			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Ivermectin			S	Oral	12 Mg, 1x		Sanofi
	Enoxaparin Sodium			S	Intravenous (not otherwise specified)	40 Mg, Qd		Sanofi
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849024	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-248623		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Product Use Issue	Hydroxychloroquine			S	Unknown	Unk (10-11 Grams)		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849173	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605500		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Graft; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Foot Operation; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849272	EXPEDITED (15-DAY)		OT	CA-ROCHE-2612226		49 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Renal Failure	Mycophenolate Mofetil	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849379	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil(Hydroxychloroquine Sulfate)			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

Remicade	S	Intravenous bolus	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849523	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004125			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Peripheral Swelling; Product Availability Issue; Unevaluable Event	Hydroxychloroquine			S		Decreased Dose		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849592	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020211375		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Multiple Organ Dysfunction Syndrome; Off Label Use	Cefepime Hcl			S		Unk		Pfizer
	Cefepime Hcl			S				Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Doxycycline Hyclate			S				Pfizer
	Linezolid			S		Unk		Pfizer
	Linezolid			S				Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk (Ds)		Pfizer
	Sulfamethoxazole/Trimethoprim			S				Pfizer
	Tobramycin			S		Unk		Pfizer
	Tobramycin			S				Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Vancomycin Hcl			S				Pfizer
	Hydroxychloroquine			S		400 Mg, 2x/Day(On Day 0)		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily(For Days 1-4)		Not Reported
	Oseltamivir			S		Unk		Not Reported

	Oseltamivir	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	400 Mg, Single (1 Dose)	Not Reported
	Lopinavir + Ritonavir	S		400 Mg, 2x/Day	Not Reported
	Lopinavir + Ritonavir	S			Not Reported
	Tacrolimus	C		6 Mg, 2x/Day(With Goal Trough Level Of 4-6 Ng/Ml)	Not Reported
	Tacrolimus	C		Unk(60% Dose Reduction)	Not Reported
	Mycophenolic Acid	C		360 Mg, 2x/Day	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	C	Intravenous (not otherwise specified)	10 G, Single	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Micafungin	C		100 Mg, Daily	Not Reported
	Heparin	C	Intravenous drip	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849861	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3426262-00		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Hepatitis Cholestatic	Kaletra 200/50			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Interferon Beta-1a			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849988	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2606400		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Rituximab			S	Intravenous (not			Not Reported

Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer			otherwise specified)		
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Apo-Ibuprofen	S	Oral		Not Reported
	Apremilast	S	Oral		Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Infliximab	S	Oral		Not Reported
	Infliximab	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Motrin [Ibuprofen]	S	Oral		Not Reported
	Motrin [Ibuprofen]	S	Oral		Not Reported

Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Otezla	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Stelara	S	Subcutaneous	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Colchicine	C	Unknown	Not Reported
Dexilant	C	Oral	Not Reported
Febuxostat	C		Not Reported
Folic Acid	C		Not Reported
Gravol	C		Not Reported
Mogadon	C	Oral	Not Reported
Nitrazepam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850007	EXPEDITED (15-DAY)		HO	ES-ACCORD-183641		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Encephalopathy; Off Label Use; Pancytopenia	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)	1 Gr Every 12 Hours X 5 Days Followed By 1gr Every 8 Hours X 6 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850039	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015789		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Diclofenac Sodium			S	Unknown			Not Reported

Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Oral	Not Reported
	Actemra	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850040	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015790		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Topicort			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
	Salazopyrin	C		Not Reported
	Tofacitinib Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850043	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015774		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Valeant
	Hydrocortisone			S	Oral			Valeant

Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Topicort	S	Subcutaneous		Not Reported
	Topicort	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown	Not Specified	Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Not Specified	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported

	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Atasol [Paracetamol]	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850045	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-015778		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter	Diclofenac			S	Unknown			Not Reported
	Topicort			S	Cutaneous			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Salazopyrin	C	Unknown	Not Reported

	Atasol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850051	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil (Hydroxychloroquine Phosphate)			S	Unknown			Not Reported

	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850058	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015796		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)	
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850061	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015809		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Desoximetasone			S	Unknown			Not Reported
	Glumetza			S	Unknown			Santarus
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Subcutaneous Solution		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Acetaminophen	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Arava	C	Unknown		Not Reported
Asa	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
D-Alpha Tocopherol	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850062	EXPEDITED (15-DAY)		DS	CA-BAUSCH-BL-2020-015814		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Topicort			S	Cutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850071	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606989		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850123	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212816			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporosis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Mycophenolate Mofetil	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850127	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212675		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Enbrel			S	Unknown	50 Mg		Unknown
	Methotrexate Sodium			S	Oral	17 Mg		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Daily		Pfizer
	Sulfasalazine			S	Unknown	1.5 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Hydroxychloroquine			C	Unknown	300 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	300 Mg		Not Reported
	Prednisone			C	Unknown	10 Mg, Daily		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850129	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020212802		58 YR	Male	CAN

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

Blindness Unilateral; Condition Aggravated; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Xeljanz	S	Unknown	5 Mg, 2x/Day		Pfizer
	Arava	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Plaquenil S	S	Unknown	Unk		Not Reported
	Enbrel	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850130	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212633		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, 1 Every 1 Weeks		Pfizer
	Enbrel			S	Subcutaneous	50 Mg		Unknown
	Sulfasalazine			S	Unknown	20 Mg, 2 Every 1 Days		Pfizer
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1 Every 24 Hours		Not Reported
	Humira			S	Subcutaneous	20 Mg, 1 Every 24 Hours		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral	50 Mg, 1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850185	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606520		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Arava	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rocuronium Bromide	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850357	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020214596			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Cimzia			S	Unknown	200 Mg, 1 Every 2 Weeks		Not Reported
	Cimzia			S	Unknown	200 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Arava			C	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown	40 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850417	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212807			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Methotrexate Sodium			S		Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850433	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241768		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	60 Mg		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850438	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242746		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis;	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Sciatica; Sinusitis; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850525	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242831			Female	CAN

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

					otherwise specified)				
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Piroxicam			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850535	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242908		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850545	EXPEDITED (15-DAY)		HO, LT	IT-ACCORD-183867		88 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Hypertransaminasaemia; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850620	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426267-00		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850937	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242799		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Not Reported
	Cyclophosphamide			S	Unknown	150 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242756		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851342	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242665		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S				Teva
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Mycophenolate Sodium			S	Unknown	1440 Milligram Daily;		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	150 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Cymbalta			C	Unknown			Not Reported

	Domperidone	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851365	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242757		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242848			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851483	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242904			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851519	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851520	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242758		71 YR	Female	CAN

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

	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851523	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242818			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851555	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1242208		15 YR	Female	USA

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

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Tachycardia	Hydroxychloroquine		S	Oral	Approximately 10-11 Gram	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851593	EXPEDITED (15-DAY)		DE	CA-ROCHE-2610888		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851659	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020206955		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Hydroxyzine Hydrochloride			S	Intravenous (not otherwise specified)	25 Mg Every 6 Hours		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851672	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020212770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Codeine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Endocervical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851705	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported

Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Topicort	S	Subcutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851707	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606940		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Pollakiuria; Product Dose Omission	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851753	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851764	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426540-00		59 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Long Qt Syndrome	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851794	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606340			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Triamcinolone Hexacetonide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851809	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2020-AMRX-01271			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851835	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609717		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606524		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852095	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043010		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram (2 In Every 1 Day)		Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852176	EXPEDITED (15-DAY)		DE, HO	ES-ROCHE-2612707		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Bundle Branch Block Right; Hypertension;	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Hydroxychloroquine			S				Not Reported

Hypofibrinogenaemia; Pneumonia Escherichia; Ventricular Tachycardia	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Tocilizumab		S			Not Reported
	Azitromicina		S	Intravenous (not otherwise specified)	500 Mg Dia	Not Reported
	Azitromicina		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852203	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426275-00		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Long Qt Syndrome	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853043	EXPEDITED (15-DAY)		HO	ES-ROCHE-2609940		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haemolytic Anaemia; Hepatitis; Hyperbilirubinaemia; Rectal Haemorrhage	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Dolquine			S	Oral	400 Mg Dia		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1gr Cada 8 Horas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853056	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported

Erythematosus	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853719	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426767-00		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder	Kaletra 200/50			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853720	EXPEDITED (15-DAY)		HO	LU-ABBVIE-20K-098-3426807-00		74 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Nimbex			S	Intravenous (not otherwise specified)	10mg/5ml		Not Reported
	Ceftriaxone Kabi			S	Intravenous (not otherwise specified)			Not Reported
	Propofol			C	Intravenous (not otherwise specified)			Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Paracetamol			C				Not Reported

	Clexane	C	Subcutaneous		Not Reported
	Simvastatine	C	Oral	Long Term Treatment, Continued	Not Reported
	Nexiam	C	Intravenous (not otherwise specified)		Not Reported
	Sufenta	C	Intravenous (not otherwise specified)	50 Microgrammes/10 Ml	Not Reported
	Lysomucil	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853744	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3427722-00		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia; Hypertransaminasaemia	Kaletra 200/50			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853748	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426655-00		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Kaletra 200/50			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853749	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3427730-00		33 YR	Male	ESP

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

Gamma-Glutamyltransferase Increased; Hypertriglyceridaemia	Kaletra 200/50		S	Oral	Not Reported
	Hidroxicloroquina Sulfato		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Systemic Lupus Erythematosus	Arava		S	Unknown	Unk	Not Reported
	Cetrizine		S	Unknown	Unk	Not Reported
	Cortisone Acetate		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Folic Acid		S	Unknown	Unk	Not Reported
	Fosamax		S	Other	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	12913342	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092065		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk, Qmo		Bristol Myers Squibb
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	50 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	4.0 Milligram/Kilogram		Not Reported

Actemra	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1 Gram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	300 Milligram, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1 Gram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Milligram, Qd	Not Reported
Methotrexate	C	Oral	Unk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram	Not Reported
Methotrexate	C	Unknown	0.8 Milliliter, Qwk	Not Reported
Xeljanz	C	Oral	5 Gram, Bid	Not Reported
Tocilizumab	C	Endocervical	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	14921384	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043876		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	14979598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2135227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	152.0 Days		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported

	Methotrexate	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Hydromorphone Hcl	C	Unknown	Not Reported
	Tylenol With Codeine No.3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15809559	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616794-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Victim Of Crime	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	16388804	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050997		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Treatment Failure; Visual Impairment	Adalimumab	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown	20.0 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400.0 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	C	Subcutaneous	15.0 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Sulfasalazine	C	Oral	1.0 Gram, Qd	Not Reported
	Xeljanz	C	Oral	5.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17024990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459482		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Off Label Use; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Sulfate] Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17154604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Subcutaneous			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Solutiom		Not Reported
Sulfasalazine	S	Oral			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Adalimumab	S	Subcutaneous			Not Reported
Cetirizine Hydrochloride	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17206018	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Drug Ineffective; Flank Pain; Leukaemia; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17209201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17259832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513906		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17359891	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532661			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Gamastan	S	Intramuscular		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Immunoglobulins (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulins (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Tetanus Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17412591	EXPEDITED (15-DAY)		HO	CA-ROCHE-1866268		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17660317	NON-EXPEDITED			US-PFIZER INC-2020147388		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off	Azithromycin			S		Unk		Pfizer

Label Use; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Hydroxychloroquine Sulfate		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17681180	EXPEDITED (15-DAY)		DS, HO, LT, OT	NVSC2020SK101566			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios; Premature Baby	Metoprolol Tartrate			S	Transplacental	Unk		Novartis
	Etamsylate			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Acetaminophen (Paracetamol)			S	Transplacental	Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Folic Acid			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Bisoprolol Fumarate			S	Transplacental	Unk		Not Reported
	Fluconazole			S	Transplacental	Unk		Not Reported
	Omeprazole			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Penicillin G Benzathine			S	Transplacental	Unk		Not Reported
	Cefotaxime			S	Transplacental	Unk		Not Reported
	Cefotaxime			S	Transplacental	Unk		Not Reported
	Hydrocortisone			S	Transplacental	Unk		Not Reported
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Magnesium Lactate			S	Transplacental	Unk		Not Reported

Bisulepin	S	Transplacental	Unk		Not Reported
Nadroparine	S	Transplacental	Unk		Not Reported
Privigen	S	Transplacental	Unk		Not Reported
Privigen	S	Transplacental	Unk		Not Reported
Flebogamma Dif	S	Transplacental	Unk		Not Reported
Vitamin B Complex	S	Transplacental	Unk		Not Reported
Vitamin B Complex	S	Unknown	Unk		Not Reported
Albumin	S	Transplacental	Unk		Not Reported
Ornidazole	S	Transplacental	Unk		Not Reported
Cefixime	S	Transplacental	Unk		Not Reported
Vulmizolin	S	Transplacental	Unk		Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Unk		Not Reported
Vitamin D	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17758901	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2020182222		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hepatic Artery Occlusion; Hepatic Infarction; Hepatic Perfusion Disorder; Hepatocellular Injury; Hypoxia; Liver Function Test Abnormal; Off Label Use; Product Use Issue	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Piperacillin/Tazobactam			S	Intravenous drip	4.5 G, 3x/Day		Pfizer
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Intravenous drip	1.2 G, 4x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single		Not Reported
	Kaletra			S	Oral	400 Mg, 2x/Day		Not Reported
	Kaletra			S	Oral	400 Mg		Not Reported
	Clexane			S	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Clexane			S	Subcutaneous	40 Mg, 2x/Day		Not Reported
	Clexane			S	Subcutaneous	Unk		Not Reported
	Clexane			S	Subcutaneous	40 Mg, 2x/Day		Not Reported
	Perfalgan			S	Intravenous (not	1 Mg (Max 3xday; As		Not Reported

			otherwise specified)	Necessary)	
	Ipramol	C		Unk	Not Reported
	Temesta [Lorazepam]	C		Unk	Not Reported
	Tavanic	C		Unk	Not Reported
	Atracurium	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Dormicum [Midazolam Maleate]	C		Unk	Not Reported
	Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C		Unk	Not Reported
	Colistin	C		Unk	Not Reported
	Torasemide	C		Unk	Not Reported
	Potassium	C		Unk	Not Reported
	Benerva	C		Unk	Not Reported
	Heparin	C		Unk	Not Reported
	Solu-Medrol	C		Unk	Not Reported
	Novorapid	C		Unk	Not Reported
	Relistor	C		Unk	Not Reported
	Novasource Gi Control	C		Unk	Not Reported
	Ventoline [Salbutamol]	C		Unk (As Necessary)	Not Reported
	Movicol	C		Unk (As Necessary)	Not Reported
	Tobramycin	C		Unk	Not Reported
	Amphotericin B	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17779489	EXPEDITED (15-DAY)		OT	NL-ADVANZ PHARMA-202004005018			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Superinfection Bacterial	Hydroxychloroquine			S	Unknown	200 Mg, Tid, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia

Azithromycine	C	Unk	Not Reported
Zinc Orotate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17787974	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2020191657			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Product Use In Unapproved Indication; Ventricular Arrhythmia	Azithromycin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17818973	EXPEDITED (15-DAY)		HO	US-ABBVIE-20K-163-3413423-00		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Anaemia; Heart Rate Increased; Heart Rate Increased; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852401	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2020021831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Monthly (Qm)		Not Reported
	Arava			S		20 Milligram		Not Reported
	Benzalkonium Chloride			S				Not Reported

Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Benzalkonium Chloride	S		Unk	Not Reported
	Diphenhydramine Hydrochloride	S		Unk	Not Reported
	Phenylephrine Hydrochloride	S			Not Reported
	Boric Acid	S			Not Reported
	Diphenhydramine Hydrochloride	S			Not Reported
	Disodium Edetate	S			Not Reported
	Enbrel	S	Subcutaneous	40 Milligram, Weekly (Qw)	Not Reported
	Gold	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phenylephrine Hydrochloride	S		Unk	Not Reported
	Rho D Immune Globulin	S			Not Reported
	Rituximab	S			Not Reported
	Simponi	S			Not Reported
	Sodium Borate	S		Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	5 Milligram- 2 Every One Week	Not Reported
	Tofacitinib Citrate	S		10 Milligram-2 Every One Week	Not Reported
	Tofacitinib Citrate	S		5 Milligram-2 Every One Week	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Prednisone	C			Not Reported
	Lipitor	C	Oral	10 Milligram, Once Daily (Qd)	Not Reported
	Ibuprofen	C	Oral	400 Milligram	Not Reported

	Celebrex	C	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852411	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligarm Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Xeljanz	C		Not Reported
Simponi	C		Not Reported
Prednisone	C		Not Reported
Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852903	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201701-000493			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly 50 Mg,Qw		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	200 Mg (Qow)		Not Reported
	Humira			S	Unknown	40 Mg (Qow)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (Qw)		Not Reported
	Leucovorin			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Coversyl			C		Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853277	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2608694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853750	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043107		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Milligram, 2 Every 1 Week		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853844	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043063			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853872	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027229		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertriglyceridaemia; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853956	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005079			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Z-Pak			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853974	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005087			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854012	EXPEDITED (15-DAY)		OT	AR-GLAXOSMITHKLINE-AR2020AMR089296		54 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Muscular Weakness; Paraparesis; Ulcer; Walking Aid User	Belimumab			S		400 Mg, Z, Monthly		Glaxosmithkline
	Omeprazole			S		Unk		Glaxosmithkline
	Vitamin D3			S		Unk		Glaxosmithkline
	Mycophenolic Acid			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methylprednisone Dose Pack			S		360 Unk		Not Reported
	Ibandronate			S		Unk		Not Reported
	Pregabaline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854014	EXPEDITED (15-DAY)		OT	AR-GLAXOSMITHKLINE-		52 YR	Female	ARG

AR2020AMR090165

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Dna Antibody Positive; Erythema; Fatigue; Leukopenia; Mouth Ulceration; Muscle Injury; Nasal Ulcer; Pericardial Effusion; Pleural Effusion; Proteinuria; Uveitis; Weight Decreased	Benlysta			S		920 Mg, Z, Monthly		Glaxosmithkline
	Vitamin D			S		Unk		Glaxosmithkline
	Ranitidine			S		Unk		Glaxosmithkline
	Folic Acid			S		Unk		Glaxosmithkline
	Azathioprine			S		Unk		Glaxosmithkline
	Mycophenolate Mofetil			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methylprednisone Dose Pack			S		Unk		Not Reported
	Isoniazid			S		Unk		Not Reported
	Trimethoprim-Sulfamethoxazole			S		Unk		Not Reported
	Methotrexate			S		20 Mg, Z, Weekly		Not Reported
	Naproxene			S		Unk		Not Reported
	Angiotensin-Converting Enzyme Inhibitor			S		Unk		Not Reported
	Enalapril			S		Unk		Not Reported
	Influenza Vaccine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854051	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Intolerance; Fatigue; Mental Disorder; Muscle Injury; Myalgia; Off Label Use; Product Use In Unapproved Indication;	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Pruritus; Rash

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854123	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027235		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	Unk		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854253	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2160			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854357	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606672		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854527	EXPEDITED (15-DAY)		DS	GB-ACCORD-183964		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hypotension; Off Label Use	Hydroxychloroquine			S				Not Reported
	Mirabegron			C				Not Reported
	Amoxicillin			C				Not Reported
	Digoxin			C				Not Reported
	Paracetamol			C				Not Reported
	Adcal-D3			C				Not Reported
	Bisoprolol			C				Not Reported
	Omeprazole			C				Not Reported
	Dabigatran/Dabigatran Etexilate			C				Not Reported
	Alendronate Sodium/Alendronic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854611	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005090			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854624	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027228		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azithromycin			S	Oral	Unk		Aurobindo
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854633	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027233		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder	Azithromycin			S	Oral	Unk		Aurobindo
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855319	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1053154		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Off Label Use	Azithromycin			S	Oral	500 Mg Cada 24h		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Unknown	No Especificada		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg C/12 Horas		Mylan

				Seguido De 200 Mg C/12 Horas	
	Hidroxicloroquina /00072601/	S			Mylan
	Lopinavir/Ritonavir	S	Oral	400 Mg C/12 Horas, 120 Tablets (Blister)	Mylan
	Lopinavir/Ritonavir	S			Mylan
	Atacand	C		28 Tablet	Mylan
	Parizac /00661201/	C		20 Capsules	Mylan
	Carduran Neo	C		28 Tablets	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607377		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855708	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606600		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported

	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Topicort [Desoximetasone]	S	Oral	Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous	Not Reported
	Topicort [Desoximetasone]	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S		Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855717	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1242988		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Ivermectina (7778a)			S	Oral	12 Mg, 4 Cp Day		Not Reported
	Enoxaparina (2482a)			S	Intravenous (not otherwise specified)	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported

Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606575			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856045	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042318			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram (1 Every 1 Month)		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk (Unknown Dosage Form)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram (4 Every 1 Week)		Not Reported
	Enbrel			S	Subcutaneous	25 Unk		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Subcutaneous	5 Milligram, Qwk		Not Reported
	Infliximab			S	Unknown	3 Milligram/Kilogram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Kilogram, Qwk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral	3 Milligram		Not Reported
	Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Milligram		Not Reported
	Triamcinolone			S	Unknown			Not Reported

	Triamcinolone Hexacetonide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Rituximab			S	Unknown	4.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856207	EXPEDITED (15-DAY)		DE	FR-FRESENIUS KABI-FK202005528		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856253	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042245		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Vomiting	Enbrel	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Baclofen	C	Unknown	Unk	Not Reported
	Estradiol	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Levaquin	C	Unknown	Unk	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Xalatan	C	Ophthalmic	Unk	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856322	EXPEDITED (15-DAY)		OT	CA-ROCHE-2612975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Rivotril			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Hydrochloride			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Prednisone			S	Unknown				Not Reported
	Zantac			S	Unknown				Not Reported
	Zopiclone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856414	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Intravenous (not otherwise specified)			Janssen
	Simponi Iv			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856591	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-036909		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Palpitations; Stress	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Hydroxychloroquine			S	Oral	200 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856622	EXPEDITED (15-DAY)		OT	CA-SA-2020SA137771			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Mycobacterium Tuberculosis Complex Test Positive	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Rosuvastatin Calcium			S		Unk		Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Plaquenil			S		200 Mg, Qd		Sanofi
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Nexium [Esomeprazole Sodium]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857193	EXPEDITED (15-DAY)		OT	NVSC2020CA153343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Cosentyx			S	Unknown			Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857388	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043555		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Oral	1 Gram		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857410	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043499			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857427	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043537			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858727	DIRECT	Y	DE			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858758	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Sudden Death	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	12137035	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-014026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Orencia			S	Unknown	1 Df, Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	12321013	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745426		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use As Prefilled Syring		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	13611477	NON-EXPEDITED			US-PFIZER INC-2017243599			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Unknown

	Methotrexate Sodium	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported
	Rituxan	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15615412	EXPEDITED (15-DAY)		DS, LT, OT	CA-APOTEX-2016AP016280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live	Apo Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo Folic Acid			S	Unknown	15 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo Prednisone Tab 1mg Usp			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	50 Mg, Unk		Apotex
	Prednisone			S	Unknown	400 Mg, Unk		Apotex
	Prednisone			S	Unknown	1 Mg, Unk		Apotex
	Prednisone			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Urethral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Cetirizine			S	Oral	10 Unk, Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Qd		Apotex
	Cetirizine			S	Unknown	25 Mg, Unk		Apotex

Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wheezing; Wound	Apo-Prednisone	S	Unknown	1 Mg, Unk	Apotex
	Apo-Prednisone	S	Unknown	5 Mg, Unk	Apotex
	Apo-Prednisone	S	Oral	Unk	Apotex
	Acetaminophen	S	Unknown	Unk	Apotex
	Folic Acid	S	Unknown	1 Unk, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Oral	25 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Oral	5 Mg, Unk	Not Reported
	Folic Acid	S	Oral	1 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Alendronate	S	Oral	Unk	Apotex
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Mg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 Df, Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported

Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Desoximetasone	S	Unknown	25 Mg, Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk, Intra Corpus Cavernosum	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Mg, Unk	Not Reported
Humira	S	Sunconjunctival	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Unk, Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Intracardiac	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Oral	500 Mg, Unk	Not Reported
Phthalylsulfathiazole	S	Oral	1000 Mg, Bid	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk Unk, Qd	Not Reported

Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Oral	1 Df, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Mg, Unk	Not Reported
Cortisone	S	Topical	25 Mg, Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Cutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Mg, Unk	Not Reported

Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 G, Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone	S	Oral	25 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Mg, Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Unknown	Unk	Not Reported
Topicort /00028604/	S	Other	Unk	Not Reported
Zyrtec /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Oral	1 G, Bid	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported

Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	1 Df, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
Folic Acid	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Actemra	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydrocortisone	S	Oral	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 G, Qd	Not Reported
Sulfasalazine	S			Not Reported
Salazopyrine	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15630696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105381		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Indometacin			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15694039	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/18/0105952		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Tacrolimus			S	Transplacental			Not Reported
	Tacrolimus			S				Not Reported
	Azathioprine			S	Transplacental			Not Reported

	Azathioprine	S			Not Reported
	Prednisone	S	Transplacental		Not Reported
	Prednisone	S			Not Reported
	Hydroxychloroquine	S	Transplacental		Not Reported
	Hydroxychloroquine	S			Not Reported
	Betamethasone	C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	16718777	EXPEDITED (15-DAY)		DS	CA-ABBVIE-18K-028-2461768-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17370427	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17583547	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Folic Acid	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17678265	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002747			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Bid, Tablet, (For One Day Followed By 200mg Twice Daily For Four Days)		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Azithromycin			S				Not Reported
	Apixaban			C		5 Mg, Bid		Not Reported
	Metoprolol Succinate			C		25 Mg, Qd		Not Reported
	Flecainide			C		50 Mg, Bid		Not Reported
	Flecainide			C		100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17721927	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003827			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Off Label Use; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia
	Enoxaparin			C		Unk		Not Reported

	Cefotaxime	C	Unk	Not Reported
	Spiramycin	C	Unk	Not Reported
	Paracetamol	C	Unk	Not Reported
	Noradrenaline [Norepinephrine]	C	2.4 Mg/Hour	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17739722	EXPEDITED (15-DAY)		HO, OT	BE-ADVANZ PHARMA-202004004406			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haemolysis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400mg 2x/D Day 1 Then 200mg 2x/D Day 2 To Day 5 (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17743985	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437137		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Asprin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17780260	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505923		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Investigation Abnormal; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Plaquenil /00072602/	S	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17796109	EXPEDITED (15-DAY)		DE, OT	BE-ADVANZ PHARMA-202004005128			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Product Use Issue; Respiratory Failure; Wrong Technique In Product Usage Process	Hydroxychloroquine			S	Oral	2 Dosage Form, Bid Capsule		Concordia
	Hydroxychloroquine			S	Oral	1 Dosage Form, Bid,Capsule		Concordia
	Hydroxychloroquine			S	Oral	2 Dosage Form, Bid, Capsule		Concordia
	Hydroxychloroquine			S	Oral	1 Dosage Form, Bid,Capsule		Concordia
	Hydroxychloroquine			S	Oral	1 Dosage Form, Bid, Capsule		Concordia
	Kevzara			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Kevzara			S				Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported
	Sarilumab Autoinjector			S				Not Reported
	Azithromycin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Cefuroxime			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Clopidogrel Sandoz			C		Unk		Not Reported
	Inderal			C		Unk		Not Reported
	Perindopril			C		Unk		Not Reported
	Morphine Hydrochloride			C		Unk		Not Reported
	Sodium Chloride			C		Unk, Morphine Hydrochloride Mixed With Sodium Chloride		Not Reported

Dafalgan Forte	C	Unk	Not Reported
Dafalgan Forte	C		Not Reported
Dafalgan Forte	C		Not Reported
Paracetamol B Braun	C	Unk	Not Reported
Clexane	C	60/0.6 Mg/Ml	Not Reported
Clexane	C	60/0.6 Mg/Ml	Not Reported
Simvastatine	C	Unk	Not Reported
Pantomed	C	Unk	Not Reported
Basaglar	C	Unk	Not Reported
Novorapid	C	Unk	Not Reported
Haldol	C	2 Mg/Ml	Not Reported
Midazolam B Braun	C	5 Mg/Ml	Not Reported
Sodium Chloride	C	Unk,Midazolam Hydrochloride In Sodium Chloride	Not Reported
Remergon	C	Unk	Not Reported
Tamsulosin	C	Unk	Not Reported
Ciproxin	C		Not Reported
Cymbalta	C		Not Reported
Coversyl	C	Unk	Not Reported
Asaflow	C		Not Reported
Contramal	C		Not Reported
Sildenafil Sandoz	C		Not Reported
Zocor	C	Unk	Not Reported
Mirtazapine	C	Unk	Not Reported
Lantus	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17812671	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517502		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract;	Remicade			S	Intravenous (not			Janssen

Cataract Operation; Drug Ineffective			otherwise specified)	
	Celebrex	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17836584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604914		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen;Codeine Phosphate	C		Not Reported
	Folic Acid	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Pregabalin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857481	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043563			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	3.0 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50.0 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857648	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Foot Deformity; Hand Deformity; Intentional Product Use Issue; Joint Swelling; Leukopenia; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Prednisone			C				Not Reported
	Solu-Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857655	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02614		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Cryptococcal	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Fingolimod			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857771	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005278			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857815	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005881			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Child-Pugh-Turcotte Score Abnormal; Non-Alcoholic Steatohepatitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857823	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607038		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Failure	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857958	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-2169			Female	CAN

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

Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Endocervical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608812		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Intentional Product Use Issue; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C		Not Reported
Arava	C		Not Reported
Codeine	C		Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858021	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606496		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858025	EXPEDITED (15-DAY)		OT	CA-SA-2020SA141648			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Live Birth; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S		50 Mg		Not Reported
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported

Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S				Not Reported
Cortisone Acetate	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858040	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005930			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858929	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020212017		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypokalaemia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859219	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243540			Male	CAN

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

Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859308	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005082			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859385	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859513	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Ibuprofen	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859514	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859528	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2180		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Pneumonia	Xeljanz		S	Oral	Not Reported
	Arava		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859534	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2172		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Condition Aggravated; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859539	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2184		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Ray Abnormal	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Penicillin G	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859544	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2186			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

	Depo-Medrol	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859563	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243624		51 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859574	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1243850			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Akathisia; Anxiety; Anxiety; Nightmare	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243571			Female	CAN

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

Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859880	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859921	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609229		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Actemra			S	Unknown			Not Reported

Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859933	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005085			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

	Zinc	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860288	EXPEDITED (15-DAY)		DS	FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL001307			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Furosemide			S	Oral	Unk		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Atorvastatin Calcium			S	Oral	Unk		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Duloxetine Hydrochloride			S	Oral	Unk		Not Reported
	Morphine Sulfate			S	Oral	Unk		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Forlax			S	Oral	Unk		Not Reported
	Dutasteride			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Cacit Vitamine D3			S	Oral	Unk		Not Reported
	Salazopyrin			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860327	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202005006128			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; General Physical Health Deterioration; Loss Of Personal Independence	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Kevzara			S	Intravenous (not otherwise specified)	400 Mg, Qd (Single Dose)		Not Reported

In Daily Activities	Ramipril		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Amlor		C		Unk	Not Reported
	Gutron		C		Unk	Not Reported
	Imeth		C		Unk	Not Reported
	Allopurinol		C		Unk	Not Reported
	Folic Acid		C		Unk	Not Reported
	Lovenox		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860394	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000448			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hepatocellular Injury; Off Label Use	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Pantoprazole Sodium			S	Oral	20 Mg, Qd		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860458	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1054257		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azithromycin			S	Unknown	500 Milligram, On Day 1		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Three Times A Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860780	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Doxycycline			C				Not Reported
	Sulfasalazine			C				Not Reported
	Tobramycin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860864	EXPEDITED (15-DAY)		DE, HO	GR-MYLANLABS-2020M1053729		51 YR	Male	GRC

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

Off Label Use; Shock	Azithromycin	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Mylan
	Anakinra	S	Intravenous (not otherwise specified)	200 Milligram, Q8h	Mylan
	Teicoplanin	S	Unknown	Unk	Mylan
	Meropenem	S	Unknown	Unk	Mylan
	Hydrocortisone	C	Intravenous (not otherwise specified)	300 Milligram, Qh	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860882	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243461		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860902	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243082		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860985	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1054146		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Coma; Hypotension; Tachycardia	Glyceryl Trinitrate			S	Topical	5 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Mylan
	Digoxin			S	Intravenous (not otherwise specified)	Unk, Every		Mylan
	Metamizole			S	Intravenous (not otherwise specified)	1 Gram Every 8 Hour		Mylan
	Paracetamol			C	Intravenous (not otherwise specified)	1 Gram Every 8 Hour		Mylan
	Pantoprazole			C	Oral	40 Milligram, Qd		Mylan
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Milligram, Qd		Mylan
	Piperacilina + Tazobactam			C	Intravenous (not otherwise specified)	4 Gram Every 8 Hour		Mylan
	Amoxicillin Clavulanic Acid			C	Intravenous (not otherwise specified)	2 Gram Every 8 Hour		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861051	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142138			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus;	Desoximetasone			S	Oral			Sanofi
	Arava			S	Oral			Sanofi
	Methotrexate			S	Oral	25 Mg		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Hydroxychloroquine			S	Oral	25 Unk		Sanofi
	Plaquenil			S	Oral			Sanofi

Swelling; Systemic Lupus Erythematosus	Folic Acid	S		500 Mg	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Apo-Prednisone	S		5 Mg	Not Reported
	Actemra	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Fosamax	S			Not Reported
	Humira	S		40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861056	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus	Desoximetasone			S	Oral			Sanofi
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Diclofenac Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine			S				Sanofi

Erythematosus; Wound	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Intra-arterial	25 Mg		Not Reported
	Sulfasalazine	S		500 Mg		Not Reported
	Pseudoephedrine Hydrochloride	S				Sanofi
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Actemra	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S				Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Hydroxychloroquine Phosphate	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861182	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020212030		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Off Label Use; Product Use In Unapproved Indication; Purpura Senile; Rash; Rash Erythematous; Rash Pruritic; Senile Pruritus	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861353	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243470			Female	CAN

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

Drug Ineffective; Drug Intolerance; Nausea	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Intramuscular	12.5 Milligram Daily;	Barr
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Intramuscular		Barr
	Arava		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Arava		S	Unknown		Not Reported
	Arava		S	Unknown	10 Milligram Daily;	Not Reported
	Arava		S	Unknown	4.2857 Milligram Daily;	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861386	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243681			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Zostavax	S	Subcutaneous		Not Reported
	Zostavax	S	Intravenous (not otherwise specified)		Not Reported
	Cortisone Acetate	C	Subcutaneous		Not Reported
	Desoximetasone	C	Subcutaneous		Not Reported
	Diclofenac	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral	20 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861398	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142306			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Desoximetasone			S				Sanofi
	Cortisone Acetate			S		25 Mg		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	25 Mg		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Sarilumab			S				Sanofi
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Pseudoephedrine	S				Not Reported
Cimzia	S				Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	4 Mg		Not Reported
Orencia	S				Not Reported
Phthalylsulfathiazole	S				Not Reported
Reactine [Cetirizine Hydrochloride]	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S				Not Reported
Simponi	S				Not Reported
Stelara	S				Not Reported
Topicort [Desoximetasone]	S				Not Reported
Xeljanz	S		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861427	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Spinal Pain; Vomiting	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861457	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243238			Female	CAN

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

Intolerance; Nausea	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Unknown		Barr
	Methotrexate		S	Unknown		Barr
	Methotrexate		S	Unknown		Barr
	Methotrexate		S	Unknown		Barr
	Methotrexate		S	Intramuscular		Barr
	Methotrexate		S	Subcutaneous		Barr
	Arava		S	Oral		Not Reported
	Arava		S	Oral		Not Reported
	Arava		S	Oral		Not Reported
	Arava		S	Oral		Not Reported
	Arava		S	Oral		Not Reported
	Arava		S	Oral		Not Reported
	Arava		S	Oral	10 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861495	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243102		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis;	Methotrexate			S	Unknown			Barr

Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861610	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1243669		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Methotrexate			S	Unknown			Barr
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861615	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	12.5 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

	Methotrexate	S	Intramuscular		Barr
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861817	EXPEDITED (15-DAY)		OT	NVSC2020FR155119		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Azithromycin			S	Other	Cf Commentaires		Novartis
	Plaquenil			S	Other	Cf Commentaires		Not Reported
	Primperan			S	Intravenous drip	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861865	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043659			Female	CAN

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

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861915	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607904			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Celecoxib			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861921	EXPEDITED (15-DAY)		OT	NVSC2020FR153002		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired	Amoxicillin Trihydrate + Potassium Clavulanate			S	Unknown	Unk		Novartis
	Amoxicillin Trihydrate + Potassium Clavulanate			S				Novartis
	Amoxicillin Trihydrate +			S				Novartis

Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Potassium Clavulanate					
	Plaquenil		S	Unknown	2 Df, Q12h (Bid,One In Morning And One In Evening)	Not Reported
	Plaquenil		S	Unknown	3 Df	Not Reported
	Plaquenil		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17862406	NON-EXPEDITED			NVSC2020US156293			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17862412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043984			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Sulfasalazine			C	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863471	EXPEDITED (15-DAY)		OT	NVSC2020CA153559			Male	CAN

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

Dyspnoea; General Physical Health Deterioration; Ill-Defined Disorder; Inflammation; Mobility Decreased; Musculoskeletal Stiffness; Pain; Pulmonary Toxicity; Therapeutic Response Decreased	Erelzi	S	Subcutaneous	50 Mg, Qw		Novartis
	Methotrexate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	5 Df		Not Reported
	Cortisone	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported
	Ibuprofen	C	Unknown	Unk		Not Reported
	Plaquenil	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863576	EXPEDITED (15-DAY)		DS	CA-ROCHE-2609041		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Increased; Drug Ineffective; General Physical Health Deterioration; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Osteoarthritis; Pain; Physical Disability; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; White Blood Cell Count Increased	Rituximab			S	Intravenous (not otherwise specified)	1.0 Months		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	5.0 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Unknown	2.0 Months		Not Reported
	Humira			S	Subcutaneous	4.0 Years		Not Reported
	Etanercept			S	Subcutaneous	610.0 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863631	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2021813US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hyperkalaemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Zithromax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864449	DIRECT	Y	LT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Liver Function Test Increased; Pneumonia	Lacosamide			S	Oral			Not Reported
	Atorvastatin			C				Not Reported
	Clobazam			C				Not Reported
	Lacosamide			C				Not Reported
	Vancomycin			C				Not Reported
	Doxycycline			C				Not Reported
	Aztreonam			C				Not Reported
	Tigecycline			C				Not Reported
	Hydroxychloroquine 200mg			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	14682648	EXPEDITED (15-DAY)		HO	CA-ROCHE-2089239		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	2 Years		Not Reported
	Certolizumab Pegol			S	Subcutaneous	15 Days		Not Reported
	Certolizumab Pegol			S	Subcutaneous	1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	2 Months	Not Reported
	Methotrexate Sodium	S	Subcutaneous	2 Months	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	2 Months	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Amlodipine	C	Unknown		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C			Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported
	Tofacitinib Citrate	C			Not Reported
	Viread	C	Unknown		Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	15974800	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Abatacept			S	Subcutaneous	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16286005	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-044948		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	9 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported

Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Every 1 Day	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Plaquenil S	S	Unknown	200 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	9 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Etanercept	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Cortisone	C	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16462022	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein	Apo-Acetaminophen			S	Unknown	Unk		Apotex

Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Apotex
	Hydroxychloroquine	S	Oral	200 Mg, Unk	Apotex
	Acetaminophen	S	Unknown	325 Mg, Unk	Apotex
	Apo-Prednisone	S	Unknown	20 Ng, Unk	Apotex
	Leflunomide	S	Unknown	200 Mg, Qd	Apotex
	Leflunomide	S	Oral	20 Mg, Qd	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	10 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk (4 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	40 Mg, Unk (4 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	50 Mg, Qd	Not Reported
	Enbrel	S	Unknown	40 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Unknown	200 Mg, Unk	Not Reported
	Orencia	S	Unknown	750 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	500 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Synthroid	C			Not Reported
Acetaminophen/Codein Phosphate	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	25 Df, Q.Wk.	Not Reported
Methotrexate	C	Unknown	Unk Unk, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Tylenol With Codeine No.3	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Tylenol With Codein #3	C	Unknown	Unk	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16859793	EXPEDITED (15-DAY)		OT	CA-ROCHE-1844081		60 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17633498	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160217144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17656876	EXPEDITED (15-DAY)		LT	US-PFIZER INC-2020148479		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Azithromycin			S	Oral	500 Mg, Daily (500 Mg On Day 1)		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily (Followed By 250 Mg Daily For 4 Days)		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day (400 Mg Twice Daily On Day 1)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (Followed By 400 Mg Daily For 4 Days)		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17729811	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020171785		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Off Label Use; Pancreatitis Acute; Product Use In Unapproved Indication	Linezolid			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Ambisome [Amphotericin B]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17741494	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020171727		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Ceftriaxone			S				Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17776859	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233507		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Rash	Azitromicina (7019a)			S	Oral	250 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Nordimet 22,5 Mg Solucion Inyectable En Pluma Precargada, 4 Plumas Pre			C	Subcutaneous	1 Iny Sc On Monday		Not Reported
	Isdiben 20 Mg Capsulas Blandas , 50 Cápsulas			C	Oral	1 Cp Every 48 Hours, 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17845832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606678		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Deformity; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Endocervical	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17853947	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-249092		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Form, Daily		Sun
	Plaquenil			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17862547	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17862613	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243656			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported

	Ergocalciferol		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Hydrodiuril		C	Unknown		Not Reported
	Neurontin		C	Unknown	1800 Milligram Daily;	Not Reported
	Premarin		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863062	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3432027-00		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia; Long Qt Syndrome	Lopinavir/Ritonavir			S	Oral	200 Mg/50 Mg Comprimido		Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Azitromicina			S	Unknown			Not Reported
	Atorvastatina			C	Oral			Not Reported
	Telmisartan/Hidroclorotiazida Alter			C	Oral			Not Reported
	Metformina			C	Oral	50 Tablet		Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863097	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610150		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Lung Disease; Irritable Bowel Syndrome; Off Label Use	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Esomeprazole Sodium	C	Unknown	Not Reported
	Lumigan Rc	C	Ophthalmic	Not Reported
	Pseudoephedrine Hydrochloride	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610708		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863327	EXPEDITED (15-DAY)		DS	CA-ROCHE-2611039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863361	NON-EXPEDITED			NVSC2020US156006			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863699	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005271			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863740	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142059			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Leflunomide			S	Oral			Sanofi
	Cortisone Acetate			S				Not Reported
	Folic Acid			S				Not Reported
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S	Oral	25 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Oral			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Hydroxychloroquine	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863889	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042794		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Unknown	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863916	EXPEDITED (15-DAY)		OT	CA-ROCHE-2143212		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Supeudol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864008	EXPEDITED (15-DAY)		HO, OT	BN-IPCA LABORATORIES LIMITED-IPC-2020-BN-001787			Unknown	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qt Prolonged; Hypocalcaemia	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Lopinavir/Ritonavir			C	Unknown	500 Milligram, Bid		Not Reported
	Tamiflu			C	Unknown	75 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864149	NON-EXPEDITED		OT	NL-AMGEN-NLDSP2020087555			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Methotrexate			S	Subcutaneous	15 Mg, Cyclical		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864276	EXPEDITED (15-DAY)		HO, OT	BN-IPCA LABORATORIES LIMITED-IPC-2020-BN-001788			Unknown	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Lopinavir/Ritonavir			C	Unknown	500 Milligram, Bid		Not Reported
	Tamiflu			C	Unknown	75 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864406	EXPEDITED (15-DAY)		DS	CA-ROCHE-2610750		48 YR	Female	CAN

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

Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Indocid [Indometacin]	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864512	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1243643		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Zostavax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864636	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609924		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tylenol	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Folic Acid	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Ebastine	C		Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864847	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020217978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swollen Joint Count Increased; Tender Joint Count Increased	Methotrexate Sodium			S	Unknown	15 Mg		Pfizer
	Celebrex			S	Oral	100 Mg, Twice Daily		Pfizer
	Folic Acid			S	Oral	1 Mg, Once Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Once Daily		Not Reported
	Leflunomide			S	Unknown	10 Mg		Not Reported
	Naproxen			S		500 Mg, Twice Daily		Not Reported
	Ergocalciferol			C	Oral	25 Ug, Once Daily		Not Reported
	Lansoprazole			C	Oral	30 Mg, Once Daily		Not Reported
	Paroxetine Hydrochloride			C	Oral	20 Mg, Once Daily		Not Reported
	Prazosin Hydrochloride			C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864865	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1053810		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Covid-19; Pyrexia	Prednisone			S		8 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864872	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170817785		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865021	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling;	Methotrexate			S	Unknown			Barr

Malaise; Multiple Sclerosis; Nausea; Vomiting	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865055	EXPEDITED (15-DAY)		CA, OT	CA-TEVA-2020-CA-1243644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865056	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243647		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865058	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865418	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure;	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Vomiting	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865433	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	17 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865440	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243861			Female	CAN

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

Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate	S	Other	Barr
	Methotrexate	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865447	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244124			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865496	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243991			Female	CAN

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

Drug Ineffective; Drug Intolerance; Malaise; Multiple Sclerosis; Vomiting	Methotrexate	S	Unknown		Barr
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Acetaminophen	C			Not Reported
	Cannabis Sativa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865875	NON-EXPEDITED			US-PFIZER INC-2020220001		49 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866034	EXPEDITED (15-DAY)		OT	NVSC2020CA156639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866127	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866259	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1244491		46 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain	Hidroxicloroquina Ratiopharm 200 Mg Co Mprimidos Recubiertos Con Pelicu			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866347	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-18737			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Etanercept			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866428	EXPEDITED (15-DAY)		DE, HO, OT	ES-009507513-2006ESP000064		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrial Fibrillation; Cardiac Failure; Death; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Respiratory Failure	Ertapenem Sodium			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lopinavir (+) Ritonavir			S		Unk		Not Reported
	Lopinavir (+) Ritonavir			S				Not Reported
	Lopinavir (+) Ritonavir			S				Not Reported
	Azithromycin			S		Unk		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Methylprednisolone Acetate			S		Unk		Not Reported
	Methylprednisolone Acetate			S		Lower Doses (+/- 1mg/Kg Per Day)		Not Reported
	Methylprednisolone Acetate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866550	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243645			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866551	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243650			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866553	EXPEDITED (15-DAY)		CA	CA-TEVA-2020-CA-1243636		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Indometacin			S	Unknown			Actavis
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	25 Milligram Daily;		Not Reported

Enbrel	S	Unknown			Not Reported
Humira	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Not Reported
Methotrexate	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
Cymbalta	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243686		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Feeling Abnormal; Immunodeficiency; Impaired Quality Of Life; Joint Swelling; Nausea; Paralysis; Polymyalgia Rheumatica; Somnolence; Synovitis; Wrist Surgery	Methotrexate			S	Unknown			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown	4 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Methotrexate			S	Unknown			Barr

C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866584	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Methotrexate			S	Other			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Codeine			C				Not Reported
	Lyrica			C				Not Reported
	Prednisone			C	Oral	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866883	EXPEDITED (15-DAY)		HO	CA-ROCHE-2612220		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866938	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044382		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Injury; Synovitis; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Mobicox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866952	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243641		67 YR	Female	CAN

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

	Azathioprine	C	Not Reported
	Ergocalciferol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867269	EXPEDITED (15-DAY)		OT	CH-MALLINCKRODT-T202002543		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hepatocellular Injury; Hypoxia	Ofirmev			S	Intravenous (not otherwise specified)	1 Milligram, Prn		Mallinckrodt
	Augmentin			S	Intravenous drip	1.2 Gram		Not Reported
	Plaquenil			S	Oral	800 Milligram (In Total)		Not Reported
	Kaletra			S	Oral	400 Milligram		Not Reported
	Kaletra			S	Oral	400 Milligram		Not Reported
	Clexane			S	Subcutaneous	40 Milligram		Not Reported
	Clexane			S	Subcutaneous	40 Milligram		Not Reported
	Clexane			S	Subcutaneous	Unk		Not Reported
	Clexane			S	Subcutaneous	40 Milligram		Not Reported
	Piperacilline/Tazobactam			S	Intravenous drip	Unk		Not Reported
	Zithromax			S	Oral	500 Milligram		Not Reported
	Ipramol			C	Unknown	Unk		Not Reported
	Temesta			C	Unknown	Unk		Not Reported
	Tavanic			C	Unknown	Unk		Not Reported
	Atracurium			C	Unknown	Unk		Not Reported
	Fentanyl			C	Unknown	Unk		Not Reported
	Dormicum			C	Unknown	Unk		Not Reported
	Phosphate			C	Unknown	Unk		Not Reported
	Torasemide			C	Unknown	Unk		Not Reported
	Potassium			C	Unknown	Unk		Not Reported
	Benerva			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported

	Solu-Medrol	C	Unknown	Unk		Not Reported
	Novorapid	C	Unknown	Unk		Not Reported
	Relistor	C	Unknown	Unk		Not Reported
	Novasource Gi Control	C	Unknown	Unk		Not Reported
	Ventoline	C	Unknown	Unk		Not Reported
	Movicol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867658	EXPEDITED (15-DAY)		OT	NVSC2020CA156677			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867699	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613104		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Hydroxychloroquine			S				Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867705	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433903-00		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Hypertriglyceridaemia	Kaletra 200/50			S	Oral	Comprimidos Recubiertos Con Pelicula, 120 Comprimidos		Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867957	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA154431		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	1 Df, Unknown		Not Reported
	Naproxen Sodium			S	Oral	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5.0 Mg, Bid		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone Acetate			S	Unknown	Unk		Not Reported

	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	12.5 Mg, Unknown	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid (2 Every 1 Day)	Not Reported
	Xeljanz	S	Oral	50 Mg, Unknown	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg (Solution)	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd (1 Every 1 Day)	Not Reported
	Metformin	C	Unknown	2 Df, Bid (2 Every 1 Day)	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611984		64 YR	Female	CAN

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

	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611791		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Misuse; Interstitial Lung Disease; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868216	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433673-00		80 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611996		47 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16075445	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo
	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every Month		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	2.68 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	680.0 Milligram, 1 Every 1		Not Reported

Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer				Month	
	Arava	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	150 Milligram, Once A Day	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every	Not Reported

			Week	
Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 2 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	15.5milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5milligram, 1 Every 1 Week	Not Reported

Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Parenteral	50.0 Milligram, 1 Every 1 Month	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	760 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680.0 Milligram, 1 Every 4 Weeks	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
Xeljanz	C	Unknown	5 Milligram, 2 Every 1 Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16075446	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25.0 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1.0 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Sulfasalazine	S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16530325	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-212718		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Cardiotoxicity; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion; Hypertensive Cardiomyopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17307005	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2020-003529		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain;	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hcl / Pseudoephedrine Hcl			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported

Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400.0 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Two Times A Day	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, Two Times A Day	Not Reported

	Tofacitinib Citrate	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Topicort	S	Cutaneous	Unk	Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17768496	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3399487-00		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Diarrhoea; Off Label Use; Renal Impairment	Lopinavir/Ritonavir			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Linezolid			C	Intravenous (not otherwise specified)			Not Reported
	Meropenem			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17867902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement;	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dexilant			S	Oral			Not Reported
	Estrogel			S	Topical			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Methotrexate	S	Intravenous (not otherwise specified)	Therapy Duration: 0.0	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ventolin Hfa	S	Other		Not Reported
	Breo Ellipta	S	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17867908	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609861			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17867979	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611810			Female	CAN

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

Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Rituximab	S	Intravenous drip			Not Reported
	Mycophenolate Mofetil	S	Oral			Not Reported
	Mycophenolate Mofetil	S	Oral	Therapy Duration 3.0 Months		Not Reported
	Arava	S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Risedronate Sodium	S	Oral			Not Reported
	Azathioprine	C	Oral	Therapy Duration 2.0 Months		Not Reported
	Azathioprine	C	Oral	Therapy Duration 661.0 Days		Not Reported
	Azathioprine	C	Oral	Therapy Duration 5.0 Years		Not Reported
	Humira	C	Subcutaneous			Not Reported
	Ketoprofen	C	Unknown			Not Reported
	Methotrexate	C	Oral			Not Reported
	Methotrexate	C	Subcutaneous			Not Reported
	Prolia	C	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868160	EXPEDITED (15-DAY)		OT	ES-ROCHE-2614539		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported
	Azitromicina			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868361	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609748		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Rituximab			S	Intravenous drip			Not Reported
	Coumadin			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Metformin			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868411	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244290			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868531	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Other	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868533	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244238		66 YR	Female	CAN

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

Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Rheumatoid Arthritis	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown	3000 Milligram Daily;	Not Reported
	Esomeprazole	C	Unknown	40 Milligram Daily;	Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Lumigan Rc	C	Ophthalmic		Not Reported
	Lyrica	C	Unknown		Not Reported
	Sulfasalazin	C	Unknown	2000 Milligram Daily;	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown	10 Milligram Daily;	Not Reported
	Trazodone	C	Unknown	200 Milligram Daily;	Not Reported
	Valsartan	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868536	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244265			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Contraindicated Product Administered; Drug Intolerance; Maculopathy; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Unknown	50 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17359996	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533770		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 330 Days		Not Reported
	Orencia			S				Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Nortriptyline Hydrochloride			S	Oral			Not Reported
	Nortriptyline Hydrochloride			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported

Lesion; Sleep Disorder; Treatment Failure	Calcium	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Omega-3 Fatty Acids	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
	Aclasta	C		Not Reported
	Actonel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17821555	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247051		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Growth Restriction; Premature Delivery	Prednisone			S	Unknown	Unk		Sun
	Insulin			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Sun
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17868879	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611587		64 YR	Female	CAN

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

Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tylenol	C		Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone Acetate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17868884	EXPEDITED (15-DAY)		OT	ES-ROCHE-2612860		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported

	Dexketoprofeno [Dexketoprofen]	S	Intravenous (not otherwise specified)	Not Reported
	Hidroxicloroquina Sulfato	S	Oral	Not Reported
	Hidroxicloroquina Sulfato	S		Not Reported
	Azitromicina	S	Oral	Not Reported
	Azitromicina	S		Not Reported
	Paracetamol	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17868903	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613270		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azitromicina			S	Oral			Not Reported
	Azitromicina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	11888202	EXPEDITED (15-DAY)		OT	JP-ASTELLAS-2010JP003369		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Drug Reaction; Allergic Cough; Aphthous Ulcer; Arthritis; Back Pain; Back Pain; Bronchitis; Dental Caries; Diarrhoea; Diarrhoea; Drug Interaction; Dry Skin; Dyspepsia; Eczema; Enterocolitis Viral;	Tacrolimus			S	Oral			Astellas
	Tacrolimus			S	Oral			Astellas
	Tacrolimus			S	Oral			Astellas
	Tacrolimus			S	Oral			Astellas
	Lipitor			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

Hyperlipidaemia; Iron Deficiency Anaemia; Muscle Spasms; Nasopharyngitis; Nasopharyngitis; Oropharyngeal Pain; Pain In Extremity; Prescribed Overdose; Prescribed Underdose; Pruritus; Rash; Tibia Fracture	Prednisolone	S	Oral	20-5mg, Alternately/2 Days	Not Reported
	Prednisolone	S	Oral	17.5-5mg, Alternately/2 Days	Not Reported
	Prednisolone	S	Oral	15-5mg, Alternately/2 Days	Not Reported
	Prednisolone	S	Oral	12.5-5mg, Alternately/2 Days	Not Reported
	Prednisolone	S	Oral	15-5mg, Alternately/2 Days	Not Reported
	Prednisolone	S	Oral	20-5mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	5-17.5mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	5-15mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	5-12.5mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	5-20mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	5-15mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	25-5mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	5-15mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral	17.5-5mg, Alternately/2days	Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported

Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Flomox [Cefcapene Pivoxil Hydrochloride]	S	Oral		Not Reported
Flomox [Cefcapene Pivoxil Hydrochloride]	S	Oral		Not Reported
Flomox [Cefcapene Pivoxil Hydrochloride]	S			Not Reported
Zithromac	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Plaquenil S	S	Oral		Not Reported
Gaster	C	Oral		Not Reported
Baktar	C	Oral	2 Df, Twice Per Week	Not Reported
Baktar	C	Oral	2 Df, Thrice Per Week	Not Reported
Alfarol	C	Oral	0.25 Mg, Once Daily	Not Reported
Persantin-L	C	Oral		Not Reported
Isodine Gargle	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Juvela /00110502/	C	Oral		Not Reported
Juvela /00110502/	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported

Lutoral	C	Oral		Not Reported
Pariet	C	Oral	10-20 Mg Per Day	Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Fosamac	C	Oral		Not Reported
Loxonin	C	Unknown		Not Reported
Loxonin	C			Not Reported
Selbex	C	Unknown		Not Reported
Selbex	C			Not Reported
Premarin	C	Oral		Not Reported
Glakay	C	Oral		Not Reported
Mevalotin	C	Oral		Not Reported
Myser /01249201/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Myser /01249201/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Ferromia	C	Oral		Not Reported
Incremin /00023544/	C	Oral		Not Reported
Incremin /00023544/	C			Not Reported
Restamin /00000401/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Restamin /00000401/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Pl	C	Oral		Not Reported
Cocarl	C	Oral		Not Reported
Cocarl	C	Oral		Not Reported
Biofermin R	C	Oral		Not Reported
Lac-B	C	Oral		Not Reported
Lac-B	C	Oral		Not Reported
Lopemin /00384302/	C	Oral		Not Reported
Onon	C	Oral		Not Reported

	Buscopan	C	Oral		Not Reported
	Propeto	C	Topical	Unk Unk, Unknown Freq.	Not Reported
	Epadel-S	C	Oral		Not Reported
	Epadel-S	C	Oral		Not Reported
	Edirol	C	Oral	0.75 Mcg, Once Daily	Not Reported
	Imuran /00001501/	C	Oral		Not Reported
	Juvela N	C	Oral		Not Reported
	Juvela N	C	Oral		Not Reported
	Bredinin	C	Oral		Not Reported
	Bredinin	C	Oral		Not Reported
	Bredinin	C	Oral		Not Reported
	Bredinin	C	Oral		Not Reported
	Bredinin	C	Oral		Not Reported
	Indometacin	C	Topical	Unk Unk, Unknown Freq.	Not Reported
	Zetia	C	Oral		Not Reported
	Kindavate	C	Topical	Unk Unk, Unknown Freq.	Not Reported
	Hirudoid /00723701/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
	Rinderon-Vg	C	Topical	Unk Unk, Unknown Freq.	Not Reported
	Lansoprazole	C	Oral		Not Reported
	Besoften	C	Other	2 Tubes, Unknown Freq.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	13100036	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877137		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Hepatic Enzyme Increased; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Potassium Chloride	C		Not Reported
	Calcium	C	Unknown	Not Reported
	Dorzolamide	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	14228937	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748896			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported

Arava	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Oral		Not Reported
Humira	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
Humira	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown	Therapy Duration: 577.0 Nos	Not Reported
Methotrexate	S	Unknown	Therapy Duration: 5 Years	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years	Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 5.0 Years	Not Reported
Remicade	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
Simponi	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Cortisone	S	Unknown		Not Reported
Desoximetasone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15708067	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-095250		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Off Label Use	Tacrolimus			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Betamethasone			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15851696	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633984-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported
Methotrexate	C	Subcutaneous	0.8 Ml		Not Reported
Methotrexate	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15959671	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1012950			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17624677	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028539		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Increased; Joint Swelling; Renal Disorder	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Atenolol	C	Unknown	50 Milligram		Not Reported
Cozaar	C	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17662028	EXPEDITED (15-DAY)			BR-ADVANZ PHARMA-202003002623			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd, Coated Tablet		Concordia
	Puran T4			C		Unk		Not Reported
	Pregabalin			C		50 Mg		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Alektos			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17703460	EXPEDITED (15-DAY)		DS, LT, OT	FR-AUROBINDO-AUR-APL-2020-020222		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Nivaquine			S	Oral	200 Milligram, Once A Day (2-3 Cp Per Day)		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day (2-3 Tsp Per Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17727115	EXPEDITED (15-DAY)		HO, LT, OT	FR-ADVANZ PHARMA-202004004354			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Off Label Use;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd, Film-Coated Tablet		Concordia

Pneumonia;	Piperacillin	C	Unk		Not Reported
Rhabdomyolysis; Rhabdomyolysis	Amphotericine B	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17802741	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1236294		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral			Not Reported
	Plaquenil 200 Mg, Comprime Pellicule			S	Oropharingeal	200 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17831822	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005605			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cough; Covid-19; Dizziness; Dyspnoea; Fatigue; Headache; Hypoxia; Lymphopenia; Myalgia; Off Label Use; Oropharyngeal Pain; Pyrexia	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	9 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Losartan			C		25 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17835084	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200529886		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Ankylosing Spondylitis; Asthenia; Asthma; Blood Test Abnormal; Body	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Alendronate Sodium			S	Unknown			Not Reported

Temperature Decreased; Bone Lesion; Cataract; Chest Pain; Chills; Condition Aggravated; Contusion; Cough; Deep Vein Thrombosis; Diarrhoea; Dysphonia; Dyspnoea; Fall; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Gastrointestinal Pain; Heart Rate Increased; Hepatic Enzyme Abnormal; Hypersensitivity; Inappropriate Schedule Of Product Administration; Infection; Influenza; Lethargy; Limb Discomfort; Lower Respiratory Tract Infection; Morton'S Neuralgia; Muscular Weakness; Mycotic Allergy; Nausea; Neuropathy Peripheral; Oral Discomfort; Pain In Extremity; Peripheral Swelling; Productive Cough; Psoriatic Arthropathy; Respiratory Tract Congestion; Rhinorrhoea; Speech Disorder	Cosentyx	S	Subcutaneous		Not Reported
	Cosentyx	S	Subcutaneous		Not Reported
	Cosentyx	S	Subcutaneous		Not Reported
	Ergocalciferol	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	Route Also Mentioned As Subcutaneous.	Not Reported
	Methotrexate	S	Oral	Route Also Mentioned As Subcutaneous.	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	Route Also Mentioned As Subcutaneous.	Not Reported
	Methotrexate	S	Oral	Route Also Mentioned As Subcutaneous.	Not Reported
	Methotrexate	S	Intramuscular		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	Also Mentioned As Intramuscular	Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Adalimumab	S	Oral	Also Mentioned As Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Also Reported As One Every Once Week	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported

	Gold Sodium Thiomalate	S	Parenteral	Not Reported
	Gold Sodium Thiomalate	S	Intramuscular	Not Reported
	Abatacept	S	Unknown	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Naproxen	C	Unknown	Not Reported
	Plaquenil /00072602/	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Budesonide W/Formoterol Fumarate	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Cyclosporine	C		Not Reported
	Simponi	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17848603	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005603			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Fatigue; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849010	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ADVANZ PHARMA-202005005784			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cough; Covid-19; Fatigue; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Baseline, Duration 60 Months		Not Reported
	Mycophenolic Acid			S	Unknown	Unk		Not Reported
	Belatacept			S	Unknown	Unk, Postponed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849022	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005919			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Diarrhoea; Dyspnoea; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk,Duration 14 Months		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 14 Months		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849023	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005785			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

	Tacrolimus			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849041	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202004004635			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Myalgia; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk,Duration 42 Months		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 42 Months		Not Reported
	Adalimumab			S	Unknown	Unk,Duration 42 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849042	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005915			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S		Decreased Dose		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Tacrolimus			S		Decreased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849068	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005913			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Myalgia; Off	Hydroxychloroquine			S	Unknown	Unk		Concordia

Label Use; Pyrexia	Hydroxychloroquine		S			Concordia
	Prednisone		S	Unknown	Unk, Duration 38 Months	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk	Not Reported
	Belatacept		S	Unknown	Unk, Duration 38 Months	Not Reported
	Tacrolimus		S	Unknown	Unk, Duration 38 Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849175	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005788			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Diarrhoea; Lung Opacity; Off Label Use; Vomiting	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Prednisone			S	Unknown	Unk,Duration 80 Months		Not Reported
	Azithromycin			S	Unknown	Unknown		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 80 Months		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849374	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005916			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk,Duration 118 Months		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 118 Months		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869253	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1244875		58 YR	Male	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244883			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown	20 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869402	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1243575		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869409	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244882		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Estradiol			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Baclofen			C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Levaquin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869413	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244721		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C				Not Reported
	Benadryl			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin Hydrobromide			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Furosemide			C				Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Kadian			C				Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported

Oxyneo	C	Unknown	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869512	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201812-004162			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Cataract; Cataract; Dermatitis; Diarrhoea; Gastroenteritis; Inflammation; Oedema; Oliguria; Pyrexia; Shock; Steroid Diabetes; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd,Film-Coated Tablet		Concordia
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	35 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	22.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Amitriptyline Hydrochloride			S	Oral	10 Mg, Qd		Not Reported
	Prograf			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Amitiza			C		Unk		Not Reported
	Alfacalcidol			C		Unk		Not Reported

Samtirel	C		Unk		Not Reported
Nexium	C	Oral	20 Mg, Qd		Not Reported
Menatetrenone	C		Unk		Not Reported
Magmitt	C		Unk		Not Reported
Atorvastatin	C		Unk		Not Reported
Daikenchuto	C		Unk		Not Reported
Odomel	C		Unk		Not Reported
Mucosta	C		Unk		Not Reported
Bayaspirin	C	Oral	100 Mg, Qd		Not Reported
Gatiflo	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869561	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1245278			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869695	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3430358-00		51 YR	Male	CAN

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

Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869724	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613253		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Metamizol [Metamizole]			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	Dose Reduced		Not Reported
	Azitromicina			S	Oral			Not Reported
	Azitromicina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869887	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-027171		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance	Amlodipine			S	Unknown	Unk		Aurobindo
	Lidocaine			S	Intravenous (not otherwise specified)	Unk		Aurobindo

Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Lidocaine	S	Topical	Unk	Aurobindo
	Montelukast	S	Unknown	Unk	Aurobindo
	Pregabalin Capsules	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Apremilast	S	Unknown	Unk	Not Reported
	Bumetanide	S	Unknown	Unk	Not Reported
	Capsaicin	S	Topical	Unk	Not Reported
	Cimetidine	S	Unknown	Unk	Not Reported
	Clonidine	S	Unknown	Unk	Not Reported
	Diltiazem	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Ibudilast	S	Unknown	Unk	Not Reported
	Ketamine	S	Topical	Unk	Not Reported
	Ketamine	S	Oral	Unk	Not Reported
	Ketamine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Lithium Carbonate	S	Unknown	Unk	Not Reported
	Magnesium	S	Unknown	Unk	Not Reported
	Magnesium	S			Not Reported
	Memantine	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Mexiletine	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	N-Acetylcysteine	S	Unknown	Unk	Not Reported
	Naltrexone Hydrochloride	S	Unknown	4.5 Milligram, Once A Day	Not Reported
	Palmitoylethanolamide	S	Unknown	Unk	Not Reported
	Pentoxifylline	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	5 Milligram	Not Reported

Prednisone	S	Unknown	13 Milligram		Not Reported
Prednisone	S	Unknown	95 Milligram, Once A Day		Not Reported
Prednisone	S	Unknown	85 Milligram, Once A Day		Not Reported
Spironolactone	S	Unknown	Unk		Not Reported
Vitamin B 12	S	Unknown	Unk		Not Reported
Vitamin B 12	S				Not Reported
Vitamin C	S	Unknown	Unk		Not Reported
Calcitonin	C	Unknown	Unk		Not Reported
Ezetimibe	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869891	EXPEDITED (15-DAY)		HO, OT	US-VELOXIS PHARMACEUTICALS-2020VELUS-000533		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Envarsus Xr			S	Transplacental			Veloxis Pharmaceuticals
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Betamethasone			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869893	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433945-00		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Kaletra 200/50			S	Oral			Not Reported
	Atorvastatina Mabo			S	Oral	Atorvastatina Mabo 40 Mg Comprimidos Recubiertos Con Pelicula Efg, 28 Comprimidos		Not Reported

	Hidroxicloroquina Sulfato	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869907	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-027340		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder; Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis; Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection	Azithromycin			S	Unknown	Unk		Aurobindo
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869943	EXPEDITED (15-DAY)		HO	CA-ROCHE-2611504		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective;	Rituximab			S	Unknown			Not Reported

Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Mycophenolate Mofetil	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870624	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020220053			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Chest Pain; Drug Intolerance; Rheumatoid Arthritis	Demerol			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Codeine Phosphate\Phenobarbital			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870785	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005634			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg (Loading Dose)		Concordia
	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Ascorbic Acid			S	Intravenous (not otherwise specified)	6 G, Bid		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported

Azithromycin	S		500 Mg, Qd (Orogastric Tube)		Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
Tocilizumab	S		8 Mg/Kg (567mg) One Dose		Not Reported
Tocilizumab	S		Another Dose (Unknown Details)		Not Reported
Remdesivir	C		200 Mg On Day 10 (Discontinued On 12 Day)		Not Reported
Ceftazidime	C	Intravenous (not otherwise specified)	1 G, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870803	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1244971		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Atenolol			C	Oral	50 Milligram Daily;		Not Reported
	Hydrochlorothiazide			C	Unknown	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870831	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244963			Female	CAN

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

Blood Disorder; Hepatotoxicity; Pain	Methotrexate	S	Unknown	Barr
	Arava	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870906	EXPEDITED (15-DAY)		LT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044055			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown	750 Milligram, Q4wk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40.0 Milligram, Qwk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral	200 Milligram, 2 Every 1 Day		Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4wk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Milligram, 2 Every 1 Day		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871132	NON-EXPEDITED			US-AMGEN-USASP2020086744		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation; Skin Reaction	Otezla			S	Oral	30 Milligram, Bid		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871133	EXPEDITED (15-DAY)		OT	IT-AMNEAL PHARMACEUTICALS-2020-AMRX-01621		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871181	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020218407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871186	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020219909			Female	CAN

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

Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Methotrexate Sodium	S		15 Mg	Pfizer
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871194	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020218406		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Neoplasm Malignant; Osteoarthritis; Pancytopenia	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk (Therapy Duration: 365.0, As Reported)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil Sulfate			S		300 Mg, 1x/Day		Not Reported
	Elavil [Amitriptyline Hydrochloride]			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Lansoprazole			C		30 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871202	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020219912		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Deformity; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported

	Prevnar 13	C	Unknown	Unk, Single	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (1 Every 12 Hours)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871321	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245871		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Every 12 Hours Followed By 200 Mg Every 12 Hours		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Unknown	2 Gram		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Hbpmin - Heparina De Bajo Peso Molecular (Hbpm) (Sin Especificar)			C				Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			C	Oral	400 Mg Every 12 Hours, 1 Dosage Form		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			C				Not Reported
	Sintrom			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871507	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020222720		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin			S	Oral	Unk		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Every 12 Hours		Not Reported

	Hydroxychloroquine Sulfate			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871811	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020218337			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Contraindicated Product Administered; Drug Intolerance; Maculopathy; Thrombocytopenia	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S				Not Reported
	Enbrel			C		50 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872148	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020222841		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, 2x/Day (Every 12 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872321	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Ventricular Tachycardia	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			C				Not Reported
	Famotidine			C				Not Reported
	Propofol			C				Not Reported
	Amidarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872324	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Famotidine			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872329	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Tachycardia; Bundle Branch Block Left; Bundle Branch Block Right; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872331	DIRECT	Y				55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872371	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433676-00		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder;	Kaletra 200/50			S	Oral			Not Reported

Sinus Bradycardia	Dolquine	S	Oral	200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609857		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872683	EXPEDITED (15-DAY)		OT	FR-SA-2020SA145735			Unknown	FRA

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

Chronic Obstructive Pulmonary Disease; Emphysema	Plaquenil		S	Oral	200 Mg, Qd	Sanofi
	Bromazepam		S	Oral	Not Speciffied	Not Reported
	Methotrexate		S	Oral	6 Df, Qw	Not Reported
	Naproxen Sodium		S	Oral	1 Tablet In The Morning And Evening For 7 Days In Case Of Severe Pain	Not Reported
	Omeprazole		S	Oral	20 Mg	Not Reported
	Duloxetine Hydrochloride		S	Oral	60 Mg	Not Reported
	Fluoxetine Hydrochloride		S	Oral	20 Mg	Not Reported
	Imovane		S	Oral	7.5 Mg, Qd	Not Reported
	Doliprane		S	Oral	1000 Mg 3x/Day On An Ad Hoc Basis	Not Reported
	Arava		S	Oral	20 Mg, Qd	Sanofi
	Enbrel		S	Subcutaneous	25 Mg, Qw	Not Reported
	Vitamine D3 Bon		S	Oral	1 Df, Qm	Not Reported
	Izalgi		S	Oral	Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873036	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873322	EXPEDITED (15-DAY)		DE, HO, OT	ES-ABBVIE-20K-144-3435672-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Death; Escherichia Urinary Tract Infection; Renal Failure; Respiratory Disorder; Respiratory Distress	Lopinavir/Ritonavir			S	Oral			Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Methylprednisolone Acetate			S	Unknown	Lower Doses (+/- 1mg/Kg Per Day)		Not Reported
	Methylprednisolone Acetate			S	Unknown			Not Reported
	Methylprednisolone Acetate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ertapenem Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	12908779	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAXALTA-2016BLT007821			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated;	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Human Normal Immunoglobulin	S	Intravenous (not otherwise specified)	70 Gram, Unknown	Shire
	Abatacept	S	Intravenous (not otherwise specified)	200 Mg, 1x A Month	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Unknown	50 Milligram, Unknown	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, 1x/Week	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	1 Dosage Form, 1x/Day:Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Unknown	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, 2x A Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Unknown	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 1x/2wks	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 1x/Week	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 1x A Week	Not Reported
	Enbrel	S	Subcutaneous	4 Dosage Form, 1x/Week	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, 1x/Day:Qd	Not Reported
	Hydroxychloroquine	S	Oral	1 Dosage Form, 1x/Day:Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg/Kg, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, Unknown	Not Reported
Infliximab	S	Unknown	1 Dosage Form, 1x/Day:Qd	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, 1x/Week	Not Reported
Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
Methotrexate	S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1x/2wks	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
Methotrexate	S	Subcutaneous	4 Dosage Form, 1x/Week	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral	50 Mg, Tablet	Not Reported
Apo-Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
Apo-Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
Sulfasalazine	S	Oral	250 Mg, 1x A Day	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, 2x A Week	Not Reported
Tocilizumab	S			Not Reported
Triamcinolone	S	Unknown	Spray Metered Dose	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
Actemra	S	Intravenous (not	280 Milligram, Unknown	Not Reported

		otherwise specified)		
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x/2wks	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1 Every 2 Months	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x A Month	Not Reported
Orencia	S		250 Milligram, 1x A Month	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported
Prednisone	S	Oral	50 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	2 Dosage Form, 1x/Day:Qd	Not Reported
Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
Triamcinolone Hexacetonide	S	Other	Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	12.5 Milligram, 1x/Week	Not Reported
Etanercept	S	Subcutaneous	25 Milligram, 2x A Week	Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	14199197	EXPEDITED (15-DAY)		OT	PHHY2017PT168435		16 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Product Use In Unapproved Indication; Skin Toxicity	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Mycophenolate Mofetil			S				Novartis
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Cyclophosphamide			S	Unknown	375 Mg/M2, (1 Day, First Cycle Dose)		Not Reported
	Cyclophosphamide			S	Unknown	750 Mg/M2, (0d ;15 D, 2nd Cycle)		Not Reported
	Prednisolone			S	Unknown	20 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	14632688	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020006		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	200 Milligram, Qd		Not Reported
Anakinra	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	14922041	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044305		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	14923972	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported

	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	15389414	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	40 Milligram, Q2wk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1 Gram		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	15766676	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-992728		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine			S	Transplacental			Teva
	Prednisone			S	Transplacental			Actavis
	Azathioprine			S	Transplacental			Not Reported
	Betamethasone			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	15953498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012379		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown	0.8 Ml, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	15983876	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015158			Female	CAN

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

Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate		S	Unknown		Barr
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Arava		S	Unknown	10 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	16021802	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-010638		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Liver Disorder; Loss Of Employment; Malaise; Nausea; Off Label Use; Rash; Therapeutic Product Effect Decreased	Cephalexin			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Losartan Tablets			S	Unknown	Unk		Aurobindo
	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Diazide [Hydralazine Hydrochloride]			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Gliclazide	S	Unknown	Unk	Not Reported
Hctz	S	Unknown	Unk	Not Reported
Hydralazine	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Keflex	S	Unknown	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Lopresor	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Moxifloxacin Sandoz	S	Unknown	Unk	Not Reported
Penicillin	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Penicillin G	S	Unknown	Unk	Not Reported
Penicillin G Potassium	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tecta	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	50 Milligram, Two Times A Day	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Daily	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Saccharated Iron Oxide	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported

Atenolol	C	Unknown	Unk		Not Reported
Cipro	C	Unknown	Unk		Not Reported
Colchicine	C	Unknown	Unk		Not Reported
Coversyl	C	Unknown	Unk		Not Reported
Leucovorin	C	Unknown	Unk		Not Reported
Levothyroxine Sodium	C	Unknown	Unk		Not Reported
Ranitidine	C	Unknown	Unk		Not Reported
Venofer	C	Unknown	Unk		Not Reported
Veltassa	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	16079923	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05880		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone Acetonide	S	Intra-articular	, Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	16080822	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-012964			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celebrex		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported
	Sulfasalazine		S	Oral	500 Milligram, 2 Everey 1 Week	Not Reported
	Prednisone		C	Unknown	2 Milligram, Once A Day	Not Reported
	Hydromorphone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	16388054	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029815		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis;	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Gabapentin			S	Oral	100.0 Milligram, Two Times A Day		Aurobindo
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Every Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488.0 Milligram, Every Month		Not Reported
	Enbrel			S	Unknown	50.0 Milligram, Every Week		Not Reported

Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400.0 Milligram, Daily	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Every Week	Not Reported
	Myochrysine	S	Intramuscular	Unk, Every 3 Weeks	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Daily	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Diphenoxylate Hcl	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Oxycodone And Acetaminophen	C	Unknown	Unk	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	16403034	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2809805-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Enbrel	S	Unknown	823	Not Reported
	Enbrel	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo Leflunomide	S	Unknown		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Tylenol	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown		Not Reported
	Tylenol W/Codeine No. 3	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported

	Celebrex	C	Oral		Not Reported
	Leflunomide	C			Not Reported
	Codeine	C			Not Reported
	Celecoxib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	16471647	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15759		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown, Duration 366		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unknown, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Esomeprazole	C	Unknown			Not Reported
Lumigan Rc	C	Ophthalmic	Unknown, Solution Ophthalmic		Not Reported
Nexium	C	Unknown	Unknown		Not Reported
Suphedrine	C	Unknown			Not Reported
Trazodone	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Wellbutrin Xl	C	Unknown	Extended Release		Not Reported
Wellbutrin Xl	C	Unknown			Not Reported
Wellbutrin Xl	C	Unknown			Not Reported
Esomeprazole Sodium	C	Unknown	Unknown		Not Reported
Acetaminophen	C	Unknown			Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	16837772	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1111986		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension;	Pantoprazole Magnesium			S	Unknown			Teva
	Cefalexin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Teva
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Actavis
	Hctz			S	Unknown			Ivax
	Losartan			S	Unknown			Teva

Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Unknown		Barr
	Metoprolol Tartrate		S	Unknown		Actavis
	Moxifloxacin Hydrochloride		S	Unknown		Teva
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.		S	Unknown		Teva
	Plaquenil S		S	Unknown		Not Reported
	Pariet		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Levaquin		S	Unknown		Not Reported
	Hydralazine Hydrochloride		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Celebrex		S	Unknown		Not Reported
	Biaxin		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Prednisone		C	Unknown	8.5 Milligram Daily;	Not Reported
	Iron Sucrose		C	Unknown		Not Reported
	Hydroxychloroquine		C	Unknown		Not Reported
	Gold		C	Unknown		Not Reported
	Esomeprazole		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17182156	EXPEDITED (15-DAY)		OT	NVSC2019CA073777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cosentyx			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported

Deformity; Liver Injury; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported

Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Injection)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Desoximetasone	S	Unknown	Unk		Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Quetiapine	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown	Unk		Not Reported
Calcium Gluconate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17363386	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005934		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Prednisone	C	Unknown	5 Milligram, Qd		Not Reported
Prednisone	C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17577389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023448		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Indometacin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17578997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023964		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Ineffective; Drug Intolerance; General Symptom; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Mobicox	C	Unknown	15 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17579024	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qwk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Oral	2000 Milligram		Not Reported
Synthroid	C	Unknown			Not Reported
Methotrexate	C	Unknown	Unk, Qwk		Not Reported
Meloxicam	C	Unknown			Not Reported
Codeine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17623463	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342096		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Stress	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Advil /00044201/			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

	Acetaminophen			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17676221	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223885		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	2 Doses In Total, 2 Dosage Forms		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17696996	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003506			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Atrial Fibrillation; Off Label Use	Hydroxychloroquine			S		600 Mg, Qd, {Film-Coated Tablet}		Concordia
	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd, {Film-Coated Tablet}		Concordia
	Fludrocortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17697006	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004003543			Unknown	FRA

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

Acute Kidney Injury; Acute Respiratory Distress Syndrome; Condition Aggravated; Multiple Organ Dysfunction Syndrome; Off Label Use; Pneumonia Bacterial	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	600 Mg, Qd, (Film Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	1000 Mg, Qd, (Film Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	400 Mg, Qd, (Film Coated Tablet)	Concordia
	Ceftriaxone	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Insulin	C	Unk	Not Reported
	Rifamycine [Rifamycin]	C	Unk	Not Reported
	Carbomere	C	Unk	Not Reported
	Metoclopramide	C	Unk	Not Reported
	Vitamin A [Retinol]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17699692	EXPEDITED (15-DAY)		LT, OT	CH-PFIZER INC-2020161844		86 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypoglycaemia	Tazobac			S	Intravenous (not otherwise specified)	4.5 G, 3x/Day		Pfizer
	Tazobac			S	Intravenous (not otherwise specified)	2.5 G, Single		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single (In Total)		Not Reported
	Cymbalta			C	Oral	60 Mg, 1x/Day		Not Reported
	Nexium Mups [Esomeprazole Magnesium]			C	Oral	20 Mg, 1x/Day		Not Reported
	Calciparine			C	Subcutaneous	5000 Iu, 2x/Day		Not Reported
	Lantus			C	Subcutaneous	20 Iu		Not Reported
	Lantus			C	Subcutaneous	10 Iu, 1x/Day		Not Reported
	Prednisone			C	Oral	10 Mg, 1x/Day		Not Reported
	Pregabalin			C	Oral	25 Mg, 2x/Day		Not Reported

	Torasemide	C	Oral	5 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17755052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Cortisone			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Oral	5 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported

Fosamax	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	1 Gram 2 Every 1 Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfathalidine	S	Unknown		Not Reported

Topicort [Hydrocortisone Acetate]	S	Unknown	Unk		Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Unknown	5 Milligram 2 Every 1 Day		Not Reported
Cetirizine	S	Unknown	Unk		Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown			Not Reported
Salazopyrina	C	Unknown			Not Reported
Tofacitinib Citrate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17835083	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17836411	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200532831		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone; C-Reactive Protein	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Subcutaneous	Also Reported As Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17844596	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042226			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Off Label Use; Pain; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

Arava	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Leflunomide	S	Unknown	200 Milligram, 1 Every 1 Days, 4 Months		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 1every 1 Weeks, 3 Months		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, 1 Every 1 Days, 4 Months		Not Reported
Tylenol	C	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17873543	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202005005990			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Natriuretic Peptide Increased; Cardiac Failure Acute; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Daily Dose)		Concordia
	Azithromycin			S	Oral	500 Mg, Daily Dose		Not Reported
	Loxoprofen			C		Unk Unk, Tid (Every 8 Hours)		Not Reported
	Baloxavir Marboxil			C	Oral	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17873590	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005006142			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder; Arthralgia; Back Pain; Drug Ineffective; Irritable Bowel Syndrome; Pain;	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk, Citrate Free		Not Reported

Pain In Extremity; Stress;
Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17873614	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-027383		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Loss Of Employment; Off Label Use; Product Use Issue	Losartan Tablets			S	Unknown	Unk		Aurobindo
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Cephalexin			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	30 Milligram, Every Week		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, Two Times A Day		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Colchicine			C	Unknown	Unk		Not Reported
	Coversyl			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Leucovorin			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Ranitidine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17873922	EXPEDITED (15-DAY)		HO	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-051647			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Tachycardia	Hydroxychloroquine			S	Oral	Unk (10-11 G)		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17873929	EXPEDITED (15-DAY)		LT, OT	ES-AUROBINDO-AUR-APL-2020-028562		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Rezolsta			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported
	Interferon Beta-1b			S	Subcutaneous	30 Microgram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17873939	EXPEDITED (15-DAY)		DE, HO, OT	ES-AUROBINDO-AUR-APL-2020-028564		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrial	Azithromycin			S	Unknown	Unk		Aurobindo

Fibrillation; Cardiac Failure; Death; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Respiratory Failure	Azithromycin		S	Unknown	Unk	Aurobindo
	Azithromycin		S			Aurobindo
	Ertapenem Powder For Concentrate For Solution For Infusion		S	Unknown	Unk	Aurobindo
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S			Not Reported
	Lopinavir + Ritonavir		S	Unknown	Unk	Not Reported
	Lopinavir + Ritonavir		S	Unknown	Unk	Not Reported
	Lopinavir + Ritonavir		S			Not Reported
	Methylprednisolone Acetate		S	Unknown	Unk	Not Reported
	Methylprednisolone Acetate		S	Unknown	Lower Doses (+/- 1mg/Kg Per Day)	Not Reported
	Methylprednisolone Acetate		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17873997	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245815		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azitromicina (7019a)			S	Oral			Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874055	EXPEDITED (15-DAY)		LT, OT	ES-AUROBINDO-AUR-APL-2020-028561		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo

	Ceftriaxone	S	Intravenous (not otherwise specified)	1000 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once A Day	Not Reported
	Rezolsta	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Kaletra	C	Oral	2 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874056	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874059	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-028560		63 YR	Male	ESP

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

Abdominal Discomfort	Azithromycin	S	Unknown	Unk	Aurobindo
	Amoxicillin+Clavulanic Acid	S	Intravenous (not otherwise specified)	1 Dosage Form, 3 Times A Day	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Two Times A Day	Not Reported
	Lopinavir/Ritonavir	S	Oral	2 Dosage Form, Two Times A Day	Not Reported
	Atrovent	C	Respiratory (inhalation)	40 Microgram, Four Times/Day	Not Reported
	Folic Acid	C	Oral	5 Milligram, Once A Day	Not Reported
	Trimbow	C	Respiratory (inhalation)	2 Dosage Form, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874060	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1245607		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective; Multimorbidity; Off Label Use; Product Use Issue; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874074	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-028254		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874172	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245927		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Azitromicina (7019a)			S	Oral			Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874325	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swollen Joint Count Increased; Tender Joint Count Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Paroxetine Hydrochloride			C	Unknown			Not Reported
	Prazosin Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874423	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-028563		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatitis; Hypertriglyceridaemia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Two Times A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874426	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ADVANZ PHARMA-202005006011			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Dyspnoea Exertional; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874658	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245817		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertriglyceridaemia; Rhabdomyolysis	Azitromicina (7019a)			S	Oral			Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva

	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid	S	Oral	2 Dosage Forms	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874679	EXPEDITED (15-DAY)		OT	NVSC2020CA158650		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostatic Specific Antigen Abnormal; Psoriasis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Cosentyx			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Golimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17874826	NON-EXPEDITED			NVSC2020US159520			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Weight Increased	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown			Novartis
	Vitamin D			C	Unknown			Not Reported
	Zinc			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875228	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-18899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Azathioprine	S	Unknown	Unknown		Not Reported
Arava	S	Unknown	Unknown		Not Reported
Actemra	S	Unknown			Not Reported
Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Cimzia	S	Subcutaneous	Solution Subcutaneous		Not Reported
Ciclosporin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875240	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-19041		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution, Dose- Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous, Dose- Unknown		Not Reported
	Rituximab			S	Subcutaneous	Unknown		Not Reported
	Rituximab			S	Intravenous drip	Unknown		Not Reported

	Simponi	S	Subcutaneous	Solution, Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Azathioprine	C	Unknown	Unknown	Not Reported
	Ciclosporin	C	Unknown	Unknown	Not Reported
	Minocycline	C	Unknown	Unknown	Not Reported
	Penicillamine	C	Unknown	Unknown	Not Reported
	Prednisolone	C	Unknown	Unknown	Not Reported
	Prednisolone	C	Unknown		Not Reported
	Tocilizumab	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875348	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1245881		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Erythromycin			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875350	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245814		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Hypertriglyceridaemia	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875455	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3436774-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Hypertension; Inflammation; Joint Lock; Liver Function Test Increased; Mobility Decreased; Musculoskeletal Disorder; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875624	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245925		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Azithromycin (7019a)			S	Oral			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosageform		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875741	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1245645		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Macular Degeneration	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875771	EXPEDITED (15-DAY)		DE, OT	FR-TEVA-2020-FR-1246007		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Ciprofloxacine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine (Sulfate D')			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875785	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245924		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Azitromicina (7019a)			S	Oral			Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875821	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246080			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875830	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246106			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875932	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054639		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertriglyceridaemia; Off Label Use; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Hidroxicloroquina Sulfato			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875936	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054636		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Off Label Use	Azithromycin			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Hidroxicloroquina /00072603/			S	Oral	Unk		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876089	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3428157-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Intolerance; Joint Swelling; Pulmonary Toxicity; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876164	EXPEDITED (15-DAY)		HO	CN-AMNEAL PHARMACEUTICALS-2020-AMRX-01620			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate			S	Unknown	1200 Milligram, Daily, For 3 Days		Amneal
	Hydroxychloroquine Sulfate			S	Unknown	800 Milligram, Daily, Maintainance Dose		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876215	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054653		59 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome; Off Label Use	Azithromycin			S	Oral	Unk		Not Reported
	Dolquine			S	Oral	Unk		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876219	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054655		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use	Azithromycin			S	Oral	500 Mg Cada 24 Horas		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Unknown	2 Gram, Qd		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg C/12 Horas Seguido De 200 Mg C/12 Horas		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Heparine /00027701/			C		Unk		Mylan
	Lopinavir/Ritonavir			C	Oral	400 Mg C/12 Horas		Mylan
	Lopinavir/Ritonavir			C				Mylan
	Sintrom			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876230	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1054719		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Ciprofloxacin			S	Oral	Unk (Inconnue)		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	200 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876236	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1245304			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysstasia; Fine Motor Skill Dysfunction; Oral Herpes;	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Pain In Extremity; Rheumatoid Nodule; Skin Papilloma	Myochrysine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876265	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005006222			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876277	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054747		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder; Off Label Use	Azithromycin			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876279	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054752		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	Unk		Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan

	Hidroxicloroquina Sulfato	S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876284	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054750		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azithromycin			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Hidroxicloroquina Sulfato			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876339	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1054652		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Off Label Use	Azithromycin			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Mylan
	Kaletra			S	Oral	2 Dosage Form, 12 Hours		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876412	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245826		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dry Mouth; Nausea; Vomiting	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876843	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3435758-00		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Lopinavir/Ritonavir			S	Oral	200 Mg/50 Mg		Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Unknown			Not Reported
	Atrovent			C	Respiratory (inhalation)	20 Microgram		Not Reported
	Acido Folico			C	Oral			Not Reported
	Trimbow			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876917	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR202005011546		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Emphysema	Cymbalta 60mg			S	Oral	60 Mg, Unknown		Not Reported
	Prozac			S	Oral	20 Mg, Unknown		Eli Lilly And Co
	Lexomil			S	Oral	Unk, Unknown		Not Reported
	Methotrexate			S	Oral	6 Dosage Form, Weekly (1/W)		Not Reported
	Plaquenil S			S	Oral	200 Mg, Daily		Not Reported
	Apranax [Naproxen Sodium]			S	Oral	1 Dosage Form, Bid		Not Reported
	Vitamine D3 Bon			S	Oral	1 Dosage Form, Monthly (1/M)		Not Reported
	Mopral [Omeprazole Magnesium]			S	Oral	20 Mg, Unknown		Not Reported
	Izalgi			S	Oral	Unk Unk, Unknown		Not Reported

Imovane	S	Oral			Not Reported
Doliprane	S	Oral	Unk, Unknown		Not Reported
Enbrel	S	Subcutaneous	25 Mg, Weekly (1/W)		Not Reported
Arava	S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17877041	EXPEDITED (15-DAY)		OT	NVSC2020CA158644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Enthesopathy; Musculoskeletal Stiffness; Nausea; Psoriatic Arthropathy; Respiratory Failure; Rheumatoid Arthritis	Secukinumab			S	Subcutaneous	300 Mg (5months)		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Erelzi (Etanercept) 50 Mg/1 Ml Solution For Injection In Pre-Filled Au			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	2 Unk, Bid (2 Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17877987	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1245822		91 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hidroxicloroquina (2143a)			S	Oral	200 Mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	400mg/12h 1 Dia Seguido De 200mg/12h		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17878227	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17878260	EXPEDITED (15-DAY)		LT	ES-ABBVIE-20K-144-3435770-00		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury	Kaletra 200/50			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Rezolsta			S	Oral	800 Mg / 150 Mg		Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	14296309	EXPEDITED (15-DAY)		OT	PHHY2017FI186340			Female	FIN

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

Drug Ineffective; Lymphopenia; Thrombocytopenia	Methotrexate	S	Unknown	Unk		Novartis
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Prednisolone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	14493419	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5.0 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	15629303	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557369-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Prednisone		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	15741654	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594158-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	15948997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-049912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of	Orencia			S	Unknown	125 Milligram, Qwk, 7 Months		Bristol Myers Squibb
	Cyclosporine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Gabapentin	C	Oral	400 Milligram, Tid	Not Reported
	Tylenol Arthritis	C	Unknown	2 Tab, Qid	Not Reported
	Tylenol Arthritis	C	Unknown	650 Milligram, 4 Every 1 Day	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	15978299	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013830			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Qd		Not Reported

Hydroxychloroquine	S	Unknown	200 Mg, Bid		Not Reported
Methotrexate	S	Subcutaneous	20.0 Mg, Qwk		Not Reported
Prednisone	S	Oral	5.0 Mg, Qd		Not Reported
Sulfasalazine	S	Unknown	1000 Mg, Unk		Not Reported
Xeljanz	C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	15978307	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013831		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Mg, Unk		Not Reported
	Asa			C	Unknown	81 Milligram		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Lantus			C	Subcutaneous	Unk		Not Reported
	Lozide [Indapamide]			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Naprosyn [Naproxen]			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

	Ramipril		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	16649758	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2872126-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	16743894	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-056074			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Pregabalin 100 Mg Capsules, Hard			S	Unknown	1 Dosage Form, 3 Times A Day (1-1-1)		Not Reported
	Pregabalin 100 Mg Capsules, Hard			S	Unknown	100 Milligram, 3 Times A Day (300 Milligram Once A Day)		Not Reported
	Ramipril 2.5mg			S	Oral	1 Dosage Form, Two Times A Day		Aurobindo
	Ramipril 2.5mg			S	Unknown	5 Milligram, Once A Day		Aurobindo
	Sildenafil			S	Unknown	60 Milligram, Once A Day, Daily Dose		Aurobindo
	Apixaban			S	Unknown	1 Dosage Form, Two		Not Reported

			Times A Day (1-0-1)	
Apixaban	S	Unknown	2.5 Milligram, Two Times A Day (5 Milligram Once A Day)	Not Reported
Omeprazole	S	Oral	1 Dosage Form, Two Times A Day	Not Reported
Omeprazole	S	Oral	20 Milligram, Two Times A Day	Not Reported
Quensyl	S	Unknown	20 Milligram, Two Times A Day (40 Milligram, Once A Day)	Not Reported
Quensyl	S	Unknown	2 Dosage Form, Once A Day (1 Df, Bid)	Not Reported
Quensyl	S	Unknown	40 Milligram, Two Times A Day (80 Milligram Once A Day)	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Spasmolyt	S	Unknown	1 Dosage Form, Once A Day (15, Qd ((1-0-0))	Not Reported
Spasmolyt	S	Unknown	30 Milligram, Once A Day	Not Reported
Spasmolyt	S	Unknown	15 Milligram, Once A Day	Not Reported
Tocilizumab	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Volibris	S	Oral	30 Milligram, Once A Day	Not Reported
Volibris	S	Oral	1 Dosage Form, Once A Day	Not Reported
Volibris	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Lyrica	S	Unknown	100 Milligram, 3 Times A Day	Not Reported
Lyrica	S	Unknown	1 Dosage Form, 3 Times A Day (1 Df, 3x/Day (1 - 1-1))	Not Reported
Ambrisentan	S	Unknown	Unk	Not Reported

	Ambrisentan	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Once A Day	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Once A Day	Not Reported
	Eliquis	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
	Omeprazole	C	Unknown	40 Milligram, Once A Day (20 Milligram, Bid)	Not Reported
	Quensyl	C	Unknown	40 Milligram, Once A Day (20 Mg Bid)	Not Reported
	Ramipril	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
	Spasmolyt	C	Unknown	15 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	6973195	EXPEDITED (15-DAY)		OT	GXKR2009DE04088		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling; Skin Mass	Ceftriaxone			S	Unknown	Unk		Novartis
	Ceftriaxone			S	Unknown	Unk		Novartis
	Co-Trimoxazole			S	Unknown	Unk		Not Reported
	Co-Trimoxazole			S	Unknown	960 Mg, Qd		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk, Dose Reduced		Not Reported
	Prednisone			S	Unknown	Unk, Dose Increased		Not Reported
	Streptomycin			S	Unknown	Unk		Not Reported
	Streptomycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17454794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-014130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Oral	50 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17543147	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022601		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Twicw Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not	1000 Milligram, Bid		Not Reported

			otherwise specified)		
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown	360.0 Milligram, Qmo	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Ciclosporin	C	Unknown	150.0 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17576314	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023435		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol			C	Unknown	100 Milligram		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17651020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		71 YR	Female	CAN

BMS-2020-029403

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17729787	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020171239		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Propofol Infusion Syndrome	Azithromycin			S	Other	500 Mg, 1x/Day (Route Of Administration Confirmed By Nasogastric Tube)		Pfizer
	Dolquine			S	Other	400 Mg, 1x/Day (Route Of Administration Confirmed By Nasogastric Tube)		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	6.6 Mg/Kg Every Hour		Not Reported

	Dexamethasone	C	Intravenous (not otherwise specified)	4 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17746062	EXPEDITED (15-DAY)		DS, LT	FR-PFIZER INC-2020178143		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Daily, 2-3 Tablets Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17747047	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3389331-00		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Off Label Use; Vomiting	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17757965	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500978		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S		Not Reported
	Hydroxychloroquine /00072603/	S		Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17805865	EXPEDITED (15-DAY)		HO, OT	CH-IPCA LABORATORIES LIMITED-IPC-2020-CH-001562			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Haemolysis; Off Label Use	Amoxicillin & Clavulanate Potassium			S	Unknown	1.2 Gram, Qid		Not Reported
	Hydroxychloroquine			S	Unknown	600 Milligram, Single		Ipca
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17824335	EXPEDITED (15-DAY)		HO, OT	LV-PFIZER INC-2020205931		12 YR	Female	LVA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pneumonitis; Systemic Lupus Erythematosus; Weight Decreased	Methylprednisolone			S	Unknown	4 Mg, 1x/Day		Pfizer
	Roactemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Roactemra			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S		Unk, For Short Time Period (1-2 Weeks), Stopped Due To Skin		Not Reported

					Eruptions	
	Rituximab		C	Unknown	375 Mg/M2, Weekly	Not Reported
	Cyclophosphamide		C		Unk, For Short Time Period (1-2 Weeks)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17830009	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2020SE66003		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia; Inflammation; Localised Oedema; Pneumonia; Pseudomonas Infection; Quarantine; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection	Inexium			S	Intravenous (not otherwise specified)			Astrazeneca
	Tazocilline			S	Unknown	Unk		Not Reported
	Perfalgan			S	Unknown	1 G, Qid If Temprature Is Greater To 38.2		Not Reported
	Lovenox			S	Subcutaneous	Unk Unk, Bid (8000 Ui)		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Rocephine			S	Unknown	Unk		Not Reported
	Mucomyst			S	Unknown	1 Df, Qid (Sachet Sng)		Not Reported
	Dextro [Dextromethorphan Hydrobromide]			S	Unknown	Unk		Not Reported
	Catapressan			S	Unknown	Unk		Not Reported
	Claventin [Clavulanic Acid/Ticarcillin]			S	Unknown	Unk		Not Reported
	Lederfoline			S	Unknown	Unk		Not Reported
	Tavanic			S	Unknown			Not Reported
	Eupressyl			S	Unknown	Unk		Not Reported
	Fortum			S	Unknown			Not Reported
	Zithromax			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tranxene			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17832750	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005787			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Dupixent			S	Unknown	Unk		Not Reported
	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17850170	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006658		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	2000 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 G, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	750 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

Xeljanz	S	Oral	50 Mg, Bid		Not Reported
Methotrexate	S	Parenteral	Unk		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk		Not Reported
Methotrexate	S	Other	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
Xeljanz	C	Oral	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17854547	EXPEDITED (15-DAY)		OT	MT-PFIZER INC-2020214578		13 YR	Male	MLT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Immunosuppression; Off Label Use; Product Use In Unapproved Indication	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Ibuprofen			C		Unk (Regular)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17860884	EXPEDITED (15-DAY)		DE, HO, OT	GR-MYLANLABS-2020M1053730		74 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatomegaly; Hypoxia; Inflammatory Marker Increased; Off Label Use; Pyrexia; Shock; Splenomegaly	Azithromycin			S		Unk		Not Reported
	Anakinra			S	Intravenous (not otherwise specified)	200 Milligram, Q8h		Mylan
	Anakinra			S		Unk		Mylan
	Teicoplanin			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Meropenem			S		Unk		Mylan
	Hydrocortisone			C	Intravenous (not	300 Milligram, Qh		Mylan

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17860891	EXPEDITED (15-DAY)		DE, OT	GR-MYLANLABS-2020M1053731		84 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anuria; Off Label Use; Shock; Splenomegaly	Azithromycin			S		Unk		Not Reported
	Anakinra			S	Intravenous (not otherwise specified)	200 Milligram, Q8h		Mylan
	Anakinra			S		Unk		Mylan
	Teicoplanin			S		Unk		Mylan
	Meropenem			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17866998	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000465			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure Congestive; Pulmonary Embolism	Furosemide			S	Oral	40 Mg, Qd		Validus
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Heparin Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878187	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202005006163			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Hydroxychloroquine			S	Unknown	Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878319	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005311			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878334	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005331			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Zpak			S		Unk		Not Reported
	Zinc			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878337	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005333			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878361	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613004		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S				Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878383	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246260		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Hepatitis	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246782		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg		Not Reported
	Ceftriaxona (501a)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878611	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005576			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878616	EXPEDITED (15-DAY)		HO	ES-ROCHE-2614454		48 YR	Male	ESP

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

Hepatitis	Roactemra	S	Intravenous (not otherwise specified)		Not Reported
	Roactemra	S			Not Reported
	Colchicina	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878739	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005313			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Muscle Spasms; Nausea	Hydroxychloroquine			S	Unknown	Unk, Qd, Daily		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878740	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005317			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Plaquenil		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878756	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246267		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Product Use Issue; Psoriasis; Therapeutic Product Effect	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Alprazolam			C	Oral			Not Reported
	Celebrex			C	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported

Incomplete	Prednisone	C			Not Reported
	Salmeterol/Fluticason Orion	C	4 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878792	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005324			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Zpac			S		Unk		Not Reported
	Zinc			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878806	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1246303		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Lymphadenopathy; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Isoniazid			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878827	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246254		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Infection; Malaise; Nasopharyngitis; Product Dose Omission; Rheumatoid Arthritis; Tendon Rupture	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878921	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005006145			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Mycobacterium	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia

Tuberculosis Complex Test Positive	Arava	S	Unknown	20 Mg, Qd		Not Reported
	Rosuvastatin Calcium	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate	S	Unknown	20 Mg, Weekly		Not Reported
	Nexium	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878929	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009247		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Neoplasm Malignant; Osteoarthritis; Pancytopenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878997	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001807			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Ceftriaxone			S	Transplacental	Unk		Not Reported

	Azithromycin	S	Transplacental	Unk	Not Reported
	Aspirin	S	Transplacental	Unk	Not Reported
	Betamethasone	S	Transplacental	Unk	Not Reported
	Norepinephrine	S	Transplacental	Unk	Not Reported
	Norepinephrine	S	Transplacental	30 Microgram (Per Minute)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17878998	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879014	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009265		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Deformity; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prevnar 13			C	Unknown	Single		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879015	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Chest Pain; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Codeine-Phenobarbital			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879016	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009267			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Contraindicated Product Administered; Drug Intolerance; Maculopathy; Thrombocytopenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879027	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Hypersensitivity; Oedema; Skin Plaque; Urticaria	Arava		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879054	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-249003		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Premature Delivery	Ceftriaxone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879078	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001808			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Pulmonary Alveolar Haemorrhage	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Norepinephrine			S	Transplacental	Unk		Not Reported
	Norepinephrine			S	Transplacental	30 Microgram (Per Minute)		Not Reported
	Betamethasone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879357	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medro			C	Intra-articular	Suspension Intraarticula		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879360	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-249470			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Azithromycin			S	Transplacental	Unk		Sun

Pregnancy; Premature Baby	Hydroxychloroquine		S	Unknown	Unk	Ipca
	Ceftriaxone		S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879372	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-249465			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Ceftriaxone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879454	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202006006123			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Eye Disorder; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879597	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246285			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879606	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005609			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Selection Error	Hydroxychloroquine			S	Oral	Extemporaneously Prepared Oral Suspension		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879627	EXPEDITED (15-DAY)		DE	NVSC2020FR161145		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Azithromycin Sandoz			S	Oral	4 Df, Qd		Novartis
	Amoxicilline Acide Clavulanique Sandoz			S	Oral	3 Df, Qd		Not Reported
	Levofloxacine Arrow			S	Oral	2 Df, Qd		Not Reported
	Plaquenil			S	Oral	3 Df, Qd		Not Reported

Darunavir	S	Oral	1 Df, Qd		Not Reported
Lovenox	S	Subcutaneous	1 Df, Qd		Not Reported
Ritonavir	S	Oral	1 Df, Qd		Not Reported
Doliprane	S	Oral	1 Df		Not Reported
Primperan	S	Oral	1 Df		Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879724	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005006267			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cough; Covid-19; Covid-19 Pneumonia; Cytokine Release Syndrome; Dyspnoea; Off Label Use; Pyrexia; Respiratory Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Fingolimod			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879742	EXPEDITED (15-DAY)		HO	GB-ACCORD-184895		90 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral			Not Reported
	Lansoprazole			C				Not Reported
	Senna Alexandrina			C				Not Reported
	Glyceryl Trinitrate			C				Not Reported
	Apixaban			C				Not Reported
	Clopidogrel			C				Not Reported
	Furosemide			C				Not Reported
	Colecalciferol			C				Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17879845	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613877		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Enoxaparina			S	Subcutaneous			Not Reported
	Dexametasona [Dexamethasone]			S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days		Not Reported
	Dexametasona [Dexamethasone]			S				Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880027	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005006170			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Central Nervous System Lesion; Meningitis Cryptococcal; Seizure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unknown		Concordia
	Gilenya			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880047	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2020M1053688		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Allergic Cough; Aphthous Ulcer; Arthritis; Back Pain; Bronchitis; Dental Caries;	Prednisolone			S	Oral	15 Milligram, Qod		Not Reported
	Prednisolone			S	Oral	25 Milligram, Qod		Not Reported

Diarrhoea; Dry Skin; Dyspepsia; Eczema; Enterocolitis Viral; Fall; Hyperlipidaemia; Iron Deficiency Anaemia; Muscle Spasms; Nasopharyngitis; Oropharyngeal Pain; Pain In Extremity; Protein Urine Present; Pruritus; Rash; Tibia Fracture	Prednisolone	S	Oral	5-20 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-17.5 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-15 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-12.5 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-15 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-20 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-17.5 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-15 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-12.5 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-20 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-15 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-25 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-15 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	5-17.5 Milligram, Qod	Not Reported
	Prednisolone	S	Oral	17.5 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	15 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	12.5 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	10 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	15 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	12.5 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	20 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	15 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	20 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	17.5 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	15 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	12.5 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	10 Milligram, Qd	Not Reported
	Prednisolone	S	Oral	7.5 Milligram, Qd	Not Reported
	Flomox /01418603/	S	Oral	300 Milligram, Qd	Mylan

Flomox /01418603/	S	Oral	300 Milligram, Qd	Mylan
Flomox /01418603/	S	Oral	Unk Unk, Qd	Mylan
Zithromac	S	Oral	2 Gram, Qd	Mylan
Cellcept /01275102/	S	Oral	500 Milligram, Qd	Mylan
Cellcept /01275102/	S	Oral	1000 Milligram, Qd	Mylan
Cellcept /01275102/	S	Oral	1500 Milligram, Qd	Mylan
Cellcept /01275102/	S	Oral	1000 Milligram, Qd	Mylan
Cellcept /01275102/	S	Oral	1250 Milligram, Qd	Mylan
Cellcept /01275102/	S	Oral	1500 Milligram, Qd	Mylan
Cellcept /01275102/	S	Oral	2000 Milligram, Qd	Mylan
Plaquenil S	S	Oral	200 Milligram, Qd	Mylan
Prograf	S	Oral	3 Milligram, Qd	Mylan
Prograf	S	Oral	4 Milligram, Qd	Mylan
Prograf	S	Oral	5 Milligram, Qd	Mylan
Prograf	S	Oral	3 Milligram, Qd	Mylan
Lipitor	S	Oral	2.5 Milligram, Qd	Mylan
Gaster Od	C	Oral	20 Milligram	Mylan
Baktar	C	Oral	2 Df, Twice Per Week	Mylan
Baktar	C	Oral	2 Df, Thrice Per Week	Mylan
Alfarol	C	Oral	0.25 Microgram, Qd	Mylan
Persantin-L	C	Oral	300 Milligram, Qd	Mylan
Isodine Gargle	C			Mylan
Juvela /00110502/	C	Oral	150 Milligram, Qd	Mylan
Juvela /00110502/	C	Oral	400 Milligram, Qd	Mylan
Lutoral	C	Oral	4 Milligram, Qd	Mylan
Lutoral	C	Oral	4 Milligram, Qd	Mylan
Lutoral	C	Oral	4 Milligram, Qd	Mylan
Lutoral	C	Oral	4 Milligram, Qd	Mylan
Lutoral	C	Oral	4 Milligram, Qd	Mylan

Pariet	C	Oral	10-20 Milligram, Qd	Mylan
Pariet	C	Oral	10 Milligram, Qd	Mylan
Pariet	C	Oral	20 Milligram, Qd	Mylan
Pariet	C	Oral	10 Milligram, Qd	Mylan
Pariet	C	Oral	20 Milligram, Qd	Mylan
Pariet	C	Oral	10 Milligram, Qd	Mylan
Fosamac	C	Oral	5 Milligram, Qd	Mylan
Loxonin	C	Unknown	120 Milligram, Qd	Mylan
Loxonin	C	Unknown	Unk Unk, Qd	Mylan
Selbex	C	Unknown	100 Milligram, Qd	Mylan
Selbex	C	Unknown	Unk	Mylan
Premarin	C	Oral	1.25 Milligram, Qd	Mylan
Glakay	C	Oral	45 Milligram, Qd	Mylan
Mevalotin	C	Oral	5 Milligram, Qd	Mylan
Myser /00115501/	C	Topical	Unk	Mylan
Myser /00115501/	C	Topical	Unk	Mylan
Ferromia	C	Oral	50 Milligram, Qd	Mylan
Incremin /00023544/	C	Oral	2 Milliliter, Qd	Mylan
Incremin /00023544/	C			Mylan
Restamin /00000401/	C	Topical	Unk	Mylan
Restamin /00000401/	C	Topical	Unk	Mylan
Pl Combination Granules	C	Oral	3 Gram, Qd	Mylan
Cocarl	C	Oral	400 Milligram, Qd	Mylan
Cocarl	C	Oral	400 Milligram, Qd	Mylan
Biofermin R	C	Oral	3 Gram, Qd	Mylan
Lac-B	C	Oral	6 Gram, Qd	Mylan
Lac-B	C	Oral	3 Gram, Qd	Mylan
Lopemin /00384302/	C	Oral	2 Milligram, Qd	Mylan
Onon	C	Oral	225 Milligram, Qd	Mylan

Buscopan	C	Oral	10 Milligram, Qd	Mylan
Propeto	C	Topical	Unk	Mylan
Epadel-S	C	Oral	1800 Milligram	Mylan
Epadel-S	C	Oral	1800 Milligram	Mylan
Edirol	C	Oral	0.75 Microgram, Qd	Mylan
Imuran /00001501/	C	Oral	25 Milligram, Qd	Mylan
Juvela N	C	Oral	600 Milligram, Qd	Mylan
Juvela N	C	Oral	400 Milligram, Qd	Mylan
Bredinin	C	Oral	50 Milligram, Qd	Mylan
Bredinin	C	Oral	75 Milligram, Qd	Mylan
Bredinin	C	Oral	100 Milligram, Qd	Mylan
Bredinin	C	Oral	125 Milligram, Qd	Mylan
Bredinin	C	Oral	150 Milligram, Qd	Mylan
Indometacin	C	Topical	Unk	Mylan
Zetia	C	Oral	10 Milligram, Qd	Mylan
Kindavate	C	Topical	Unk	Mylan
Hirudoid	C	Topical	Unk	Mylan
Rinderon Vg	C	Topical	Unk	Mylan
Lansoprazole	C	Oral	15 Milligram, Qd	Mylan
Besoften	C	Topical	2 Tubes	Mylan
Carbocysteine	C	Oral	750 Milligram, Qd	Mylan
Tulobuterol	C		2 Milligram, Qd	Mylan
Hangeshashinto /08016601/	C	Oral	2.5 Milligram, Qd	Mylan
Hangeshashinto /08016601/	C	Oral	2.5 Milligram, Qd	Mylan
Celecox	C	Oral	100 Milligram, Qd	Mylan
Astomin /00426502/	C	Oral	30 Milligram, Qd	Mylan
Aftach	C	Unknown	Unk	Mylan

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880084	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043023		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	680 Milligram, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	360 Milligram, Qmo		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Ciclosporin			S	Unknown	150 Milligram, Qd		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram, 2 Every 1 Day		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880134	EXPEDITED (15-DAY)		DS, HO	NVSC2020CH155813		62 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Artery Thrombosis; Peripheral Ischaemia	Torasemid Sandoz 2,5 Mg Tablett			S	Oral	2.5 Mg, Qd		Not Reported
	Azithromycin Sandoz 500, Filmtabletten			S	Oral	500 Mg, Qd		Novartis
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Amlodipin Pfizer			C	Oral	10 Mg, Qd		Not Reported
	Valsartan Sandoz			C	Oral	160 Mg, Bid		Not Reported
	Remeron			C	Sublingual	7.5 Mg, Qd		Not Reported
	Co-Amoxi			C	Oral	625 Mg, Q8h		Not Reported
	Clarithromycin Sandoz			C	Oral	500 Mg, Q12h		Not Reported
	Fragmin			C	Subcutaneous	5000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880343	EXPEDITED (15-DAY)		HO	ES-ROCHE-2614404		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported
	Azitromicina			S	Oral	500 Mg Dia		Not Reported
	Lopinavir/Ritonavir			S	Oral	2u Cada 12h		Not Reported
	Lopinavir/Ritonavir			S				Not Reported

	Hidroxicloroquina Sulfato	S	Oral	400 Mg Dia		Not Reported
	Hidroxicloroquina Sulfato	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880345	EXPEDITED (15-DAY)		OT	ES-ROCHE-2614414		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880371	EXPEDITED (15-DAY)		HO	ES-ROCHE-2615275		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S				Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880721	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020223240		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertriglyceridaemia; Off Label Use; Product Use In Unapproved Indication; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Pfizer
	Kaletra			S	Oral	2 Df, 2x/Day(Every 12 Hours)		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Hydroxychloroquine Sulfate			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880813	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880974	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246149		59 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome	Azitromicina (7019a)			S	Oral			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral			Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881020	EXPEDITED (15-DAY)		HO	ES-ROCHE-2616554		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Roactemra			S	Intravenous (not	600 Mg Dia		Not Reported

			otherwise specified)			
	Privigen	S	Intravenous (not otherwise specified)	32 Gr 100 Mg / Ml Solution For Infusion, 1 Vial Of 400 Ml		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg Dia		Not Reported
	Azitromicina	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881114	EXPEDITED (15-DAY)		DE	OM-PFIZER INC-2020224530		72 YR	Male	OMN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		500 Mg, 1x/Day		Pfizer
	Meropenem			S		Unk		Pfizer
	Levofloxacin			S		Unk		Not Reported
	Teicoplanin			S		Unk		Not Reported
	Ceftriaxone			S		2 G, 1x/Day		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Interferon Beta			S		Unk		Not Reported
	Lopinavir/Ritonavir			S		Unk		Not Reported
	Cisatracurium			C	Intravenous (not otherwise specified)	Unk, Intermittent Doses		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881296	EXPEDITED (15-DAY)		OT	CN-APPCO PHARMA LLC-2085619			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881320	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020221626		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder; Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis; Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection	Methotrexate Sodium			S	Unknown			Pfizer
	Azithromycin			S	Unknown			Pfizer
	Methylprednisolone Acetate			S	Unknown			Pfizer
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881346	EXPEDITED (15-DAY)		OT	CN-APPCO PHARMA LLC-2085620			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881364	EXPEDITED (15-DAY)		OT	CN-APPCO PHARMA LLC-2085621			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Injury	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881377	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2020SE71971		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Emphysema	Mopral			S	Oral	20.0mg Unknown		Not Reported
	Lexomil			S	Oral	Not Precised		Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apranax			S	Oral	1 Tablet Morning And Evening For 7 Days In Case Of Severe Pain		Not Reported
	Vitamine D3			S	Oral			Not Reported
	Cymbalta			S	Oral	60.0mg Unknown		Not Reported
	Prozac			S	Oral	20.0mg Unknown		Not Reported
	Imovane			S	Oral			Not Reported
	Doliprane			S	Oral	1000 Mg 3 Times A Day On An Ad Hoc Basis		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881695	EXPEDITED (15-DAY)		HO	NVSC2020US159554		29 YR	Female	USA

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

Cytomegalovirus Colitis	Prednisone		S	Unknown	Unk	Novartis
	Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881820	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043516			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882161	EXPEDITED (15-DAY)		OT	NVSC2020FR161499			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown	600 Mg		Novartis
	Azithromycin			S	Unknown	500 Mg, Qd, On Day 1		Not Reported

	Azithromycin	S	Unknown	250 Mg, Qd, On Day 2 And 5		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882186	EXPEDITED (15-DAY)		LT	ES-MYLANLABS-2020M1056038		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Off Label Use	Azithromycin			S	Unknown	Unk		Not Reported
	Dolquine			S	Oral	Unk (30 Tablets)		Mylan
	Kaletra			S	Oral	Unk (120 Tablets)		Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044491			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882407	EXPEDITED (15-DAY)		LT	NVSC2020FR161310		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin Sandoz 250mg			S	Oral	500 Mg, Qd		Novartis
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882566	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043545			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	13229139	EXPEDITED (15-DAY)		HO	CA-ROCHE-1892550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	Therapy Duration: 6.0 Month(S)	Not Reported
	Apo Hydro	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride;Paracetamol	S	Unknown		Not Reported
	Doxycycline	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported

	Synthroid	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25.0 Dosage Forms Nos	Not Reported
	Celebrex	C	Oral		Not Reported
	Celecoxib	C			Not Reported
	Codeine	C			Not Reported
	Hydromorphone Hydrochloride	C			Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	13229205	EXPEDITED (15-DAY)		DS	CA-ROCHE-1892598		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Prednisone Acetate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported
Sulfasalazine	C	Oral	Not Reported
Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	13393116	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP008815			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Prednisone	C	Unknown	2 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	14906435	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1678150-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tylenol			S	Unknown	Dosage Maintained		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

Apo-Leflunomide	S	Oral		Not Reported
Methotrexate	C			Not Reported
Meloxicam	C	Unknown		Not Reported
Synthroid	C			Not Reported
Tylenol No. 3	C			Not Reported
Celebrex	C			Not Reported
Acetaminophen And Codeine Phosphate	C			Not Reported
Hydromorphone Hcl	C			Not Reported
Xeljanz	C			Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Acetaminophen And Codeine Phosphate	C			Not Reported
Celecoxib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	14911755	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-045068		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension;	Abatacept			S	Intravenous drip	250 Mg, Qmo; For 2 Months		Bristol Myers Squibb
	Abatacept			S	Nasal	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk, Cyclical; 5.0 Months		Not Reported
	Actemra			S	Subcutaneous	250 Milligram, Cyclical 6 Months		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd; 2 Years; 1 Year		Not Reported
	Anakinra			S	Subcutaneous	12.5 Milligram, Qwk; 7.0 Months		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qd, 3 Years		Not Reported

Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Poor Venous Access; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Milligram, Qwk; 3.0 Months	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk, For 4 Months	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Etanercept	S	Subcutaneous	25 Milligram, 2 Times/Wk	Not Reported
	Etanercept	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	For 2 Months	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Immune-Globulin [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 Gram, Herbal Tea	Not Reported
	Immune-Globulin [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	For 2 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, 4 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q6wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk, For 8 Months	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk, For 9 Years	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	50 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Triamcinolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	15108415	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0742		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Kineret			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	15408170	EXPEDITED (15-DAY)		DS	CA-JNJFOC-20180911342		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Peripheral Swelling; Therapy Non-Responder	Arava	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	15811306	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617216-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	16693459	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2882710-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S		Not Reported
	Rituximab	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17563205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, 3 Every 1 Day		Not Reported

	Premarin	C	Unknown		Not Reported
	Tylenol	C	Unknown	650 Milligram, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17697696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033213		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17747157	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437139		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Advil /00109201/			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac /01001802/			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

Prednisone		C	Unknown	Not Reported
Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17753230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592884		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Actemra			S	Unknown	365.0		Not Reported
	Actemra			S				Not Reported
	Hydroxychloroquine			S	Unknown	5.0 Years		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown	8.0 Years		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17765762	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437414		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Infliximab	S		Not Reported
	Plaquenil /00072602/	S		Not Reported
	Tocilizumab	S		Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17810218	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2020AMR084142		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Ketoacidosis; Malaise; Systemic Lupus Erythematosus	Benlysta			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17827643	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA2713		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Angiopathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Surgery; Venous Injury;	Kineret			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Venous Operation; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17835134	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528667			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine /00884302/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17839657	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606057		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Bifidobacterium Bifidum	C		Not Reported
	Celebrex	C		Not Reported
	Loperamide	C		Not Reported
	Pantoprazole	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17841644	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020205717		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia; Inflammation; Localised	Lederfoline			S		Unk		Pfizer
	Tazocilline			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	2 Df, 1x/Day (2x/Day (8000 Ui)		Not Reported
	Perfalgan			S		1 G, 4x/Day		Not Reported
	Bactrim			S		Unk		Not Reported
	Inexium [Esomeprazole Magnesium]			S	Intravenous (not	40 Mg, 1x/Day		Not Reported

Oedema; Pneumonia; Pseudomonas Infection; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection				otherwise specified)	
	Rocephine		S	Unk	Not Reported
	Mucomyst [Acetylcysteine]		S	4 Df, 1x/Day, (1 Df 4x/Day (Sachet Sng))	Not Reported
	Dextro [Dextromethorphan Hydrobromide]		S	Unk	Not Reported
	Catapressan [Clonidine Hydrochloride]		S	Unk	Not Reported
	Claventin [Clavulanate Potassium;Ticarcillin Disodium]		S	Unk	Not Reported
	Tavanic		S	500 Mg, 2x/Day	Not Reported
	Eupressyl [Urapidil]		S	Unk	Not Reported
	Fortum [Ceftazidime]		S	2 G, 3x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unk	Not Reported
	Tranxene		S	2.5 Mg, Per Hour	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17844767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605531		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Reaction; Arthralgia; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Minocin			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Myochrysine			S				Not Reported
	Orencia			S	Unknown			Not Reported

	Otezla	S	Oral	Not Reported
	Salazopyrina	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Ustekinumab	S	Subcutaneous	Not Reported
	Ustekinumab	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rheumatrex [Methotrexate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17873546	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003005948			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Disorder; Cardiac Failure Congestive; Chest Pain; Off Label Use; Pulmonary Embolism	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd,Film-Coated Tablet		Concordia
	Furosemide			S	Oral	40 Mg, Qd, Daily		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Heparin Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17877364	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS-2020M1055370		71 YR	Female	FRA

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

Acute Kidney Injury; Cardiac Failure Congestive; Pulmonary Embolism	Furosemide	S	Oral	40 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Mylan
	Enoxaparin	C	Subcutaneous	4000 Iu, Qd	Mylan
	Heparin Sodium	C	Intravenous (not otherwise specified)	25000 (Units Not Specified), Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17878157	EXPEDITED (15-DAY)			BR-ADVANZ PHARMA-202005006108			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Bid Film Coated Tablet On First Day		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Adjusted To)		Concordia
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd, Iv Nos		Not Reported
	Azithromycin			S				Not Reported
	Bromoprida			C		Unk		Not Reported
	Clexane			C		Unk		Not Reported
	Amiodarone Hydrochloride			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Fentanest			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Lactulona			C		Unk		Not Reported
	Luftal			C		Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Nujol			C		Unk		Not Reported
	Zinforo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883043	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005006167			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film Coate Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883123	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883172	EXPEDITED (15-DAY)		OT	FR-ROCHE-2616495		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Etomidate			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not			Not Reported

			otherwise specified)		
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Roactemra	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883197	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02749		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Pressure Decreased; Exposure During Pregnancy; Off Label Use	Ceftriaxone			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Norepinephrine			S	Unknown	Unk		Not Reported
	Norepinephrine			S	Unknown	Unk, Increased To 30 Mcg/Min		Not Reported
	Norepinephrine			S	Unknown	Unk, Decreased To 6 Mcg/Min		Not Reported
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]			C	Unknown	Unk		Not Reported
	Aspirine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883294	EXPEDITED (15-DAY)		HO	CA-ROCHE-2611688		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Intolerance; Hepatitis; Hypersensitivity; Off Label Use; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883364	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02764			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Delivery; Pulmonary Alveolar Haemorrhage	Ceftriaxone			S	Transplacental	Unk		Lupin
	Azithromycin			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Norepinephrine			S	Transplacental	Unk		Not Reported
	Norepinephrine			S	Transplacental	Unk, Increased To 30 Mcg/Min		Not Reported
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]			C	Unknown	Unk		Not Reported
	Aspirine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883365	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02763			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Covid-19; Foetal Exposure During Pregnancy; Low	Ceftriaxone			S	Transplacental	Unk		Lupin
	Azithromycin			S	Transplacental	Unk		Lupin

Birth Weight Baby; Premature Delivery	Hydroxychloroquine	S	Transplacental	Unk	Lupin
	Betamethasone	S	Transplacental	Unk	Lupin
	Norepinephrine	S	Transplacental	Unk	Not Reported
	Norepinephrine	S	Transplacental	Unk, Increased To 30 Mcg/Min	Not Reported
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]	C	Unknown	Unk	Not Reported
	Aspirine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883406	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Spinal Column Injury; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883558	EXPEDITED (15-DAY)		OT	CA-SA-2020SA148597			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis;	Plaquenil			S	Oral	400 Mg, Qd		Sanofi

Retinopathy	Arava	S	Oral	10 Mg, Qd		Sanofi
	Methotrexate	C	Oral	17.5 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883600	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1246774		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Coma; Hypotension; Tachycardia	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Metamizol (111a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Nitroglicerina (1037a)			S	Topical	5 Mg		Not Reported
	Digoxina (770a)			S	Intravenous (not otherwise specified)			Not Reported
	Paracetamol (12a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Pantoprazol (7275a)			C	Oral	40 Mg		Not Reported
	Metilprednisolona (888a)			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Piperacilina + Tazobactam			C	Intravenous (not otherwise specified)	4 Gram		Not Reported
	Amoxicilina + Aido Clavulaico			C	Intravenous (not otherwise specified)	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883764	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043800			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis; Diverticulitis; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Baclofen	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	500 Milligram, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qd	Not Reported
	Estradiol	C	Unknown	0.6 Percent, Tid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Levaquin	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Zingiber Officinale	C	Unknown	500 Milligram	Not Reported
	Xalatan	C	Ophthalmic	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883837	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-246272		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Cardiotoxicity; Ischaemic Cardiomyopathy; Muscle Atrophy; Musculoskeletal Toxicity; Syncope	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Chloroquine			S	Unknown	200 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17883990	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3437512-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pulmonary Mass; Tinnitus	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884119	EXPEDITED (15-DAY)		HO, OT	NVSC2020IR156621			Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Drug Ineffective	Hydroxychloroquine			S	Unknown			Novartis
	Oseltamivir			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884218	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247161		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes	Methotrexate			S	Unknown			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported

Zoster; Interstitial Lung Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Cannabis Sativa		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Oxycodone Hydrochloride		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884227	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	1800 Milligram Daily;		Not Reported
	Premarin			C	Unknown			Not Reported
	Tylenol			C	Unknown	1300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884294	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C		1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884317	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1247037			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Meloxicam	C	Oral		Not Reported
Prednisolone	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884319	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1247023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884343	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247081			Female	CAN

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

Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Prednisone	C	Unknown	50 Milligram Daily;		Not Reported
	Prevacid	C	Unknown			Not Reported
	Xeljanz	C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884535	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247168			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884536	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247087		40 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884676	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500969		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Joint	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S				Janssen

Swelling; Off Label Use; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Amoxicillin/Clavulanic Acid	S	Unknown	Not Reported
	Ampicillin Trihydrate	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Not Reported
	Cephalexin /00145501/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884723	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported

Desoximetasone	S	Oral			Not Reported
Enbrel	S	Unknown			Not Reported
Folic Acid	S	Unknown			Not Reported
Fosamax	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Subcutaneous			Not Reported
Reactine [Cetirizine]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituximab	S	Intravenous drip			Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247100		67 YR	Female	CAN

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

	Naproxen		C	Unknown	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884746	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1246778		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Interferon Beta-1a (2305ou)			S	Subcutaneous	30 Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885263	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034648		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Specific Antibody; Dry Eye; Feeling Abnormal; Joint Swelling; Metabolic Disorder; Sleep Apnoea Syndrome; Vitiligo	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Etanercept			S	Other	25 Milligram, Qwk		Not Reported
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Duration- 5 Years		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Duration- 4.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	2 Gram, Qd	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Methotrexate	C	Other	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885289	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170806972		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Enablex			C	Unknown	Extended-Release		Not Reported
	Plantago Ovata			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Orphenadrine Citrate			C	Unknown			Not Reported
	Omnaris			C	Unknown	Metered Dose		Not Reported
	Pantoloc			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

Vagifem	C	Vaginal	Not Reported
Vagifem	C	Vaginal	Not Reported
Ativan	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Diphenhydramine	C		Not Reported
Lasix /00032601/	C		Not Reported
Norflex /00018303/	C		Not Reported
Pantoprazole Sodium Anhydrous	C		Not Reported
Darifenacin	C		Not Reported
Furosemide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885691	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Dexamethasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported

	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885793	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1246872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885813	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247136			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885814	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1247146			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Indometacin			S	Oral	150 Milligram Daily;		Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885829	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			C	Unknown	20 Milligram Daily;		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C	Unknown	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885835	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247069		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			C	Unknown	2 Dosage Forms Daily;		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1 Dosage Forms Daily;		Not Reported
	Furosemide			C	Unknown	40 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan			C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan			C	Unknown	50 Microgram Daily;		Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885849	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246780		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	Unit Dose: 4 Dosage Forms		Not Reported

	Ceftriaxona (501a)	S	Unknown		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	Unit Dose: 400 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886063	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043870		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886065	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1055595		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Mylan
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan
	Interferon Beta-1a			S	Subcutaneous	30 Microgram, Qd		Mylan

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886074	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044428		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Dosage Form, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	1 Gram, Qd		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886114	EXPEDITED (15-DAY)		LT	NVSC2020FR162482		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	Posologie Non Connue		Novartis
	Plaquenil			S	Oral	800 Mg, Qd		Not Reported
	Augmentin			C	Oral	Posologie Non Connue		Not Reported
	Hypnovel			C	Unknown			Not Reported
	Sufentanil			C	Unknown			Not Reported
	Etomidate			C	Unknown			Not Reported
	Tracrium			C	Unknown			Not Reported
	Esmeron			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886117	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA162296		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell	Ilaris			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Rituximab	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Mg		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Anakinra	S				Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Urelumab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886250	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1055658		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia; Off Label Use	Azithromycin			S		Unk		Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd (2 G Cada 24 H)		Mylan
	Ceftriaxona /00672201/			S				Mylan

	Lopinavir/Ritonavir	S	Oral	1 Dosage Form, Bid (400 Mg C/12 Horas)	Mylan
	Lopinavir/Ritonavir	S			Mylan
	Hidroxicloroquina /00072601/	S		Unk	Mylan
	Bufomix Easyhaler	C		Unk	Mylan
	Paracetamol	C		Unk	Mylan
	Condrosan	C		Unk	Mylan
	Vesicare	C		Unk	Mylan
	Prednisona	C		Unk	Mylan
	Alprazolam	C		Unk	Mylan
	Axiago	C		Unk	Mylan
	Atorvastatina /01326101/	C		Unk	Mylan
	Lyrica	C		Unk	Mylan
	Clexane	C		Unk	Mylan
	Lorazepam	C			Mylan
	Sintrom	C			Mylan
	Movalis	C		Unk	Mylan
	Doclis	C		Unk	Mylan
	Rivotril	C		Unk	Mylan
	Montelukast	C		Unk	Mylan
	Optovite B12	C			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886251	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1055664		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperbilirubinaemia; Long Qt Syndrome	Azithromycin			S		500 Milligram, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Bid		Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Bid		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	200 Milligram, Bid		Mylan
	Hidroxicloroquina /00072601/			S	Oral	200 Milligram, Bid		Mylan

	Hidroxicloroquina /00072601/	S	Oral	200 Milligram, Bid	Mylan
	Atorvastatina /01326101/	C	Oral	20 Milligram, Qd	Mylan
	Telmisartan And Hydrochlorothiazide	C	Oral	80 Milligram, Qd	Mylan
	Metformina /00082701/	C	Oral	850 Milligram, Q8h	Mylan
	Tocilizumab	C		600 Milligram, Total	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886375	EXPEDITED (15-DAY)		HO	ES-ROCHE-2616541		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Pulmonary Embolism	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400 Mg Dia		Not Reported
	Azitromicina			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886477	EXPEDITED (15-DAY)		DE, OT	NVSC2020IR156620			Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Exposure During Pregnancy; Hypoxia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Oseltamivir			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886729	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA162283		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Deep Vein Thrombosis;	Ilaris			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported

Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Rituximab	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Formulation: Solution Subcutaneous)	Not Reported
	Humira	S	Unknown	Unk	Not Reported

Lyrica	S	Unknown	Unk		Not Reported
Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Oxycodone	S	Unknown	10 Mg		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Xeljanz	S	Oral	1 Df, Bid (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	13147225	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004948		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	15415983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	16854707	EXPEDITED (15-DAY)		OT	CA-ROCHE-2411130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17003175	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1132141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17371160	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2538246		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17581956	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083719		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Anakinra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
	Minocycline	S	Unknown		Not Reported

	Minocycline Hydrochloride		S	Unknown		Not Reported
	Oxycodone		S	Unknown	10 Mg	Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17632164	EXPEDITED (15-DAY)		OT	NVSC2020FR079225		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Ocular Toxicity	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17658993	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030043		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unk		Not Reported

Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomida	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported

Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Kineret	C	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Urelumab	C	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17697668	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226208		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17764520	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597010		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Off Label Use	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17807800	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2598497			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S	Oral			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17815847	NON-EXPEDITED			NVSC2020US140199			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Unknown		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17820529	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Methotrexate	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Meloxicam	C	Oral	Not Reported
Prednisolone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17855560	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608742		51 YR	Female	CAN

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

			otherwise specified)	
	Methotrexate	S	Other	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17857435	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043559		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1.0 Gram		Not Reported
	Rituximab			S	Unknown	1.0 Gram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

Methotrexate	C	Subcutaneous	20 Milligram, Qd		Not Reported
Methotrexate	C	Unknown	0.8 Milliliter		Not Reported
Leflunomide	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17871286	EXPEDITED (15-DAY)		HO, LT, OT	TR-SA-2020SA143578			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Diarrhoea; Lung Opacity; Off Label Use; Pyrexia	Prednisone			S	Oral	10 Mg, Qd		Not Reported
	Thymoglobulin			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Nebivolol			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17886686	NON-EXPEDITED		OT	FR-AMGEN-FRASP2020091400		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Emphysema; Off Label Use	Enbrel			S	Subcutaneous	25 Mg, Weekly		Amgen
	Lexomil			S	Oral	Unk		Not Reported
	Methotrexate Bellon			S	Oral	6 Df, Weekly		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Apranax [Naproxen Sodium]			S	Oral	1 Tablet In The Morning And In The Evening For 7 Days In Case Of Severe Pain		Not Reported
	Vitamine D3 Bon			S	Oral	1 Df, Monthly		Not Reported

Mopral [Omeprazole Sodium]	S	Oral	20 Mg		Not Reported
Cymbalta	S	Oral	60 Mg		Not Reported
Izalgi	S	Oral	Unk		Not Reported
Prozac	S	Oral	20 Mg		Not Reported
Imovane	S	Oral	7.5 Mg, 1x/Day		Not Reported
Doliprane	S	Oral	1000 Mg, 3x/Day, On An Ad Hoc Basis		Not Reported
Arava	S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17886949	EXPEDITED (15-DAY)		OT	PE-ADVANZ PHARMA-202005005830			Unknown	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Loss Of Consciousness; Unevaluable Event	Hydroxychloroquine			S	Oral	200 Mg, Qd, Every Night Orally		Concordia
	Deflazacort			C		Unk		Not Reported
	Arcoxia			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17886952	EXPEDITED (15-DAY)		HO, OT	TW-ADVANZ PHARMA-202005006168			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Discharge; Drug Hypersensitivity; Erythema; Genital Erythema; Leukocytosis; Neutrophil Count Increased; Neutrophilic Dermatosis; Oedema; Pustule; Pyrexia; Rash;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk, Qd		Concordia
	Prednisolone			S	Unknown	Unk, Qd		Not Reported
	Imuran			S	Unknown	Unk, Qd		Not Reported

Rash Pruritic; Skin Exfoliation; Skin Plaque; Swelling Face

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17886959	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005006272			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887062	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247126		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887064	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247116		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Vaginal	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Arava	C	Oral	Not Reported
Ativan	C		Not Reported
Benadryl	C		Not Reported
Darifenacin	C	Unknown	Not Reported
Darifenacin	C	Unknown	Not Reported
Desoximetasone	C		Not Reported
Dilaudid	C		Not Reported
Diphenhydramine	C		Not Reported
Loperamide	C		Not Reported
Norflex[Orphenadrine Citrate]	C		Not Reported
Omnaris	C	Unknown	Not Reported
Pantoloc[Pantoprazole]	C		Not Reported
Pantoprazole	C	Oral	Not Reported
Plantago Ovata	C		Not Reported
Synthroid	C		Not Reported
Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887066	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247096		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Arava	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887068	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247140		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Anakinra			C				Not Reported
	Ativan			C				Not Reported
	Benadryl			C				Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C	Intra-arterial			Not Reported
	Desoximetasone			C	Intramuscular			Not Reported
	Dilaudid			C				Not Reported
	Lasix[Furosemide]			C				Not Reported
	Leflunomide			C				Not Reported

	Norflex[Orphenadrinecitrate]	C			Not Reported
	Omnaris	C			Not Reported
	Pantoprazole	C			Not Reported
	Synthroid	C			Not Reported
	Vagifem	C	Vaginal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887094	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1247147			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247153		43 YR	Female	CAN

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

Swelling	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Tramadol Hydrochloride		C	Oral		Not Reported
	Xeljanz		C	Unknown	100 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887255	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044296		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram 1 Every 24 Hours		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram 1 Every 24 Hours		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram		Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887405	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246783		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	4 Dosage Form		Not Reported

	Ceftriaxona (501a)	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887466	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619069			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887539	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619241			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective For Unapproved Indication; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887554	EXPEDITED (15-DAY)		DE	ES-ROCHE-2616496		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported

	Dexametasona [Dexamethasone]	S	Intravenous (not otherwise specified)	20 Mg Dia	Not Reported
	Enoxaparina	S	Subcutaneous	40mg Dia	Not Reported
	Dexketoprofeno [Dexketoprofen]	S	Intravenous (not otherwise specified)	25 Mg Cada 8 Horas	Not Reported
	Hidroxicloroquina Sulfato	S	Oral	400 Mg Dia	Not Reported
	Azitromicina	S	Oral	500 Mg Dia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887623	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009369		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder; Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis; Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Methylprednisolone Acetate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887651	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044384		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qmo		Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887667	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044179		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Thyroid Disorder; Treatment Failure; Vomiting	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Baclofen	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Levaquin	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17887856	EXPEDITED (15-DAY)		DS	CA-ROCHE-2620043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

	Simponi	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17888179	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2616531		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Dexametasona [Dexamethasone]			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Azitromicina			S	Oral	500 Mg Dia		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Enoxaparina			S	Subcutaneous	80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17888321	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247158		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	2.5 Milligram Daily;	Not Reported
	Enbrel	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17888441	EXPEDITED (15-DAY)		HO	CA-ROCHE-2619010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17888545	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619934		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported

	Xalatan	C	Unknown		Not Reported
	Zingiber Officinale	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17888642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619654			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17888669	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Oral	25 Milligram		Not Reported
Folic Acid	S	Unknown	5 Milligram		Not Reported
Fosamax	S	Oral			Not Reported
Humira	S	Subcutaneous	4 Milligram		Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Oral	25 Milligram		Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Sarilumab	S	Unknown			Not Reported
Simponi	S	Subcutaneous			Not Reported
Stelara	S	Unknown			Not Reported
Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day		Not Reported
Topicort [Desoximetasone]	S	Subcutaneous			Not Reported
Xeljanz	S	Unknown	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17888708	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness;	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported

Rheumatoid Arthritis; Vomiting	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, 1 Every 1 Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889068	EXPEDITED (15-DAY)		OT	ES-ACCORD-185163		29 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889071	EXPEDITED (15-DAY)		OT	ES-ACCORD-185199		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Off Label Use	Hydroxychloroquine			S	Oral	Last Dose Administered On 23-May-2020		Not Reported
	Lopinavir/Ritonavir			S	Oral	Strength:200 Mg/50 Mg Tablet		Not Reported
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)	Strength:1,000 Mg / 200 Mg Injection		Not Reported
	Azithromycin			S		Last Dose Administered On 23-May-2020		Not Reported
	Atrovent			C	Respiratory	Strength: 20 Micro		Not Reported

			(inhalation)	Grams,Inhalation Solution In Pressurized Container,1 Inhaler Of 200 Doses.	
	Folate Sodium/Folic Acid	C	Oral	Strength:5 Mg 28 Tablets	Not Reported
	Trimbow	C	Respiratory (inhalation)	Strength:87 Microgram / 5 Microgram / 9 Microgram, 1 Inhaler Of 120 Pulsations	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889144	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620244			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889310	EXPEDITED (15-DAY)		OT	NVSC2020ES162790		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Novartis
	Kaletra			S	Oral	5 Ml, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889329	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Liver Function Test Increased; Off Label Use; Physical Disability; Product Use Issue; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Celebrex			C	Oral	400 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889449	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1247242		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported

Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Morphine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889459	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247218		40 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889505	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889507	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2020-CA-1247224		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889509	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247293			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Fatigue; Joint Swelling; Nausea; Product Dose Omission; Quality Of Life Decreased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Skin Discolouration; Visual Impairment; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889544	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Diarrhoea; Hypotension; Palpitations; Supraventricular Tachycardia	Hyrdoxychloroquine (Hydroxychloroquine So4 200mg Tab)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889550	EXPEDITED (15-DAY)		DE, HO	ES-ROCHE-2616887		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Roactemra			S	Unknown			Not Reported
	Roactemra			S				Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	1gr /8h		Not Reported
	Piperacilina - Tazobactam			S	Intravenous (not otherwise specified)	C/8h		Not Reported

Metamizole	S	Intravenous (not otherwise specified)	2 Gr C/8h		Not Reported
Hidroxicloroquina Sulfato	S	Oral	400 Mg Dia		Not Reported
Linezolid	S	Intravenous (not otherwise specified)	600mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247151		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889582	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247148		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889695	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247235		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889703	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1247226		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)	1000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889711	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247227			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889716	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247219			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Cytology Abnormal; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)		
	Lyrica		C	Oral		Not Reported
	Prednisone		C	Unknown	20 Milligram Daily;	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889732	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247395			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			C		20 Milligram Daily;		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C		3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889777	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1055263		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cytomegalovirus Colitis; Cytomegalovirus Gastritis; Cytomegalovirus Gastrointestinal Ulcer; Cytomegalovirus Oesophagitis; Gastrointestinal Melanosis	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889996	EXPEDITED (15-DAY)		DE, OT	ES-BIOGEN-2020BI00885597		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Hepatitis Cholestatic; Off Label Use	Avonex			S	Subcutaneous			Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Kaletra			S	Oral	200/50 Mg		Not Reported
	Azithromycin			S	Oral			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890039	EXPEDITED (15-DAY)		OT	NVSC2020CA163319			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890097	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA162081		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd (3 Months)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1.75 Mg		Not Reported
	Acetaminofen Tramadol			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd (6 Months)		Not Reported
	Plaquenil			S	Unknown	(3 Years)Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd (2 Years)		Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Calcium			C	Unknown			Not Reported
	Calciferol			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported

Methylprednisolone Acetate	C	Unknown		Not Reported
Methylprednisolone Acetate	C	Intramuscular	Unk	Not Reported
Nortriptyline	C	Unknown		Not Reported
Nortriptyline Hydrochloride	C	Unknown		Not Reported
Premarin	C	Unknown		Not Reported
Risedronate Sodium	C	Unknown		Not Reported
Tylenol Arthritis Pain	C	Unknown		Not Reported
Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890386	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048073			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark
	Celecoxib			S	Oral	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram 1 Every 1 Month		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Od		Not Reported
	Myochrysine			S	Intramuscular	1 Every 3 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram 1 Every 1 Month		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Od		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	Unk		Not Reported

Ergocalciferol	C	Unknown	Unk		Not Reported
Esomeprazole	C	Unknown	Unk		Not Reported
Ferrous Gluconate	C	Unknown	Unk		Not Reported
Loperamide	C	Unknown	Unk		Not Reported
Nasonex	C	Unknown	Unk		Not Reported
Oxycodone	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890387	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048076			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility	Gabapentin			S	Oral	100 Milligram, Bid (2 Every 1 Day)		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	480 Milligram (1 Every 1 Months)		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qw (1 Every Weeks)		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Od (1 Every 1 Day)		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Once A Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Once In 3 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Once Every 4 Weeks		Not Reported

Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Od (1 Every 1 Day)	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Lomotil /00034001/	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Omega 3 /06852001/	C	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890388	EXPEDITED (15-DAY)		LT	ES-MYLANLABS-2020M1056302		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Rezolsta			S	Oral	1 Dosage Form, Qd		Mylan
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan
	Interferon Beta-1b			S	Subcutaneous	30 Microgram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890390	EXPEDITED (15-DAY)		LT	ES-MYLANLABS-2020M1056335		76 YR	Male	ESP

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

Atrial Fibrillation; Off Label Use	Azithromycin	S	Oral	500 Milligram, Qd	Not Reported
	Ceftriaxona /00672201/	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Mylan
	Rezolsta	S	Oral	1 Dosage Form, Qd	Mylan
	Hidroxicloroquina Sulfato	S	Oral	400 Milligram, Qd	Mylan
	Kaletra	C	Oral	2 Dosage Form, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890391	EXPEDITED (15-DAY)		DE, HO, OT	ES-MYLANLABS-2020M1056340		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrial Fibrillation; Cardiac Failure; Death; Off Label Use; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Respiratory Failure	Azithromycin			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Lopinavir/Ritonavir			S		Unk		Not Reported
	Lopinavir/Ritonavir			S		Unk		Not Reported
	Lopinavir/Ritonavir			S		Unk		Not Reported
	Methylprednisolone Acetate			S		Lower Doses (Plus /-1mg/Kg Per Day)		Mylan
	Methylprednisolone Acetate			S		Unk		Mylan
	Methylprednisolone Acetate			S		Unk		Mylan
	Hydroxychloroquine Sulfate			S		Unk		Mylan
	Hydroxychloroquine Sulfate			S		Unk		Mylan
	Hydroxychloroquine Sulfate			S		Unk		Mylan
	Ertapenem Sodium			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890435	EXPEDITED (15-DAY)		OT	NVSC2020NL164458		65 YR	Unknown	NLD

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

Abscess; Arthritis	Prednisone		S	Unknown	5 Mg		Novartis
	Plaquenil		S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247247		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890787	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247225			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Spinal Compression Fracture	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ychloroquine Sulfate (Hydroxychloroquine Sulfate)			S	Unknown			Not Reported

	Ychloroquine Sulfate (Hydroxychloroquine Sulfate)	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890799	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pseudoephedrine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890831	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1247250		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890832	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17890882	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17891294	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1043846		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Azithromycin			S				Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17891297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247238		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17891298	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1247306			Male	CAN

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

Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib	S	Unknown		Teva
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Prednisone	C	Unknown	2 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17891956	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Mycophenolate Mofetil			C	Oral			Not Reported
	Infliximab			C				Not Reported

	Lipitor	C	Unknown		Not Reported
	Metformin	C	Oral		Not Reported
	Glyburide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892089	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619009		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Desoximetasone			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892166	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619053			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619120		52 YR	Female	CAN

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

Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892418	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA164373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported

	Xeljanz			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort [Desoximetasone]			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892688	EXPEDITED (15-DAY)		HO	CA-ROCHE-2620243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Rituximab			S	Intravenous (not	Another Route:		Not Reported

Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased			otherwise specified)	Endocervical	
	Methotrexate	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	16080795	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013881		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	488 Milligram (1 Every 1 Month)		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Celebrex			S	Occlusive dressing technique	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, (Every 3 Weeks)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Once A Day		Not Reported

Aclasta	C	Intravenous (not otherwise specified)	750 Milligram	Not Reported
Actonel	C	Oral	36 Milligram, Every Week	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Diphenoxylate	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Diphenoxylate	C	Unknown	Unk, Once A Day	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Ergocalciferolum	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferolum	C	Unknown	Unk, Once A Day	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Ferrous Fumarate	C	Unknown	300 Milligram, Once A Day	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	5 Gigabecquerel, Once A Day	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported

Sodium Ascorbate	C	Unknown	Unk		Not Reported
Thiamine Hydrochloride	C	Unknown	Unk		Not Reported
Thiamine Mononitrate	C	Unknown	Unk		Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Once A Day		Not Reported
Tylenol	C	Oral	1000 Milligram, Once A Day		Not Reported
Vitamin A	C	Unknown	Unk		Not Reported
Vitamin B12	C	Unknown	Unk		Not Reported
Vitamin C	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Two Times A Day		Not Reported
Acetaminophen	C	Unknown	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17742017	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020078		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Intentional Product Use Issue; Pyrexia	Amoxicillin			S	Oral	3 Gram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	800 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17862681	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-026891		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bundle Branch Block; Conduction Disorder; Decreased Appetite; Drug Ineffective; Dysphagia; Dysphonia;	Fenofibrate			S	Unknown	100 Milligram, Daily		Aurobindo
	Chloroquine			S	Unknown	200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day (400mg Per Day 7.4 Mg/Kg/Day)		Not Reported

Left Ventricular Hypertrophy; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Weight Decreased	Ranitidine	C	Unknown	300 Milligram, Once A Day	Not Reported
	Clopidogrel	C	Unknown	75 Milligram, Once A Day	Not Reported
	Acetylsalicylic Acid	C	Unknown	75 Milligram, Once A Day	Not Reported
	Paracetamol;Tramadol	C	Unknown	Unk	Not Reported
	Aspirin Aluminium	C	Unknown	Unk	Not Reported
	Clobetasol	C	Unknown	1 Application/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17892153	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619588			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown	4.0 Years		Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17892287	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620139		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17892466	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Methotrexate	S	Oral		Not Reported
	Folic Acid	C	Unknown	1.0 Dosage Forms	Not Reported
	Prednisone	C			Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17892594	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2020-029184		73 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Torsade De Pointes	Fluconazole			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day (Only Received One Dose)		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	800 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17892807	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyarthritis; Polyarthritis; Product Use Issue	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17892896	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3443061-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Off Label Use; Toxicity To Various Agents	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Xeljanz	C		Not Reported
	Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17893068	EXPEDITED (15-DAY)		OT	FR-CANTON LABORATORIES, LLC-2085779		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Emphysema	Naprosyn			S	Oral			Canton Laboratories
	Lexomil Roche Comprime Baguette			S	Oral			Not Reported
	Methotrexate Bellon			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Vitamine D3 Bon			S				Not Reported
	Mopral			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Izalgi			S	Oral			Not Reported
	Prozac			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17881862	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044828		46 YR	Female	CAN

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

Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Methotrexate	C	Unknown	1 Milliliter, Qwk	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	7 Milligram, Qd	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17893199	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619239		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Specific Antibody; Dry Eye; Feeling Abnormal; Joint Swelling; Sleep Apnoea Syndrome; Vitiligo	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Other			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Methotrexate	C	Other	Not Reported
Methotrexate	C	Other	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17893206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619817		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

	Lantus	C	Subcutaneous	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17893209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620006			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort [Desoximetasone]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17893212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17893213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Acetaminophen	C	Unknown	Not Reported
Atacand	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Hydrodiuril	C	Unknown	Not Reported
Neurontin	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17893216	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620983			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17893217	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599643		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Reaction; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Atenolol			C	Oral			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	12914315	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093127		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Orencia			S	Intravenous (not otherwise specified)	760 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Gastric Disorder; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Tocilizumab	S	Unknown	360 Milligram, Q4wk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
	Tocilizumab	S	Unknown	360 Milligram, Qwk	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	380 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Q2wk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported

Methotrexate	S	Unknown	10 Milligram, Q4wk	Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Apo-Leflunomide	S	Oral	380 Milligram	Not Reported
Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	25 Milligram	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	360 Milligram, Qmo	Not Reported
Hydroxychloroquine	S	Unknown	680 Milligram	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Unknown	10 Milligram	Not Reported
Myochrysine	S	Unknown	50 Milligram, Qmo	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Q4wk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported

Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Ibuprofen	S	Oral	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ibuprofen	S	Oral	600 Milligram, Qd	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Etanercept	S	Unknown	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported

Naproxen	S	Unknown	Unk	Not Reported
Cyclosporin	C	Unknown	Unk	Not Reported
Cyclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	13058844	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015725		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; Fracture;	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Celecoxib			S	Unknown	Unk		Apotex

General Physical Health Deterioration; Hepatitis; Immobile; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Risedronate	S	Unknown	Unk	Apotex
	Risedronate	S	Oral	Unk	Apotex
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actonel	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	Unk, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prolia	S	Subcutaneous	Unk	Not Reported
	Prolia	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	20 G, Qd	Not Reported
	Prednisolone Sodium Phosphate	S	Unknown	Unk	Not Reported
	Prednisolone Sodium Phosphate	S	Ophthalmic	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Cyclobenzaprine	C	Unknown	10 Mg, Unk	Not Reported

	Desoximetasone	C	Unknown	5 Mg, Qd	Not Reported
	Desoximetasone	C	Unknown	5 Mg, Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Prednisone Acetate	C	Unknown	5 Mg, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	13119212	EXPEDITED (15-DAY)		HO, OT	US-SA-2017SA004994		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Drug Reaction; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Loss Of Consciousness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Photophobia; Pruritus; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S	Alprazolam			S	Oral	.5 Mg,Tid		Not Reported
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Lasix			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Isosorbide Dinitrate			S	Unknown	Unk Unk,Unk		Not Reported
	Ampicillin Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Flagyl			S	Unknown	Unk		Sanofi
	Mesalazine			S	Unknown	Unk		Sanofi
	Citalopram Hydrobromide			S	Unknown	Unk		Not Reported
	Pregabalin			S	Oral	100 Mg,Hs		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg,Qd		Not Reported
	Ziprasidone Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported
	Colchicine			S	Unknown	Unk Unk,Unk		Not Reported
	Prochlorperazine			S	Unknown	Unk Unk,Unk		Not Reported
	Acetazolamide			S	Unknown	Unk Unk,Unk		Not Reported
	Hydromorphone Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported
	Doxycycline			S	Unknown	Unk Unk,Unk		Not Reported
	Hydrochlorothiazide/Triamterene			S	Unknown	Unk Unk,Unk		Not Reported

Syndrome; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Wheezing; Wound	Erythromycin	S	Unknown	Unk Unk,Unk	Sanofi
	Hepatitis B Vaccine	S	Unknown		Not Reported
	Iron (Salt Not Specified)	S	Unknown	Unk Unk,Unk	Not Reported
	Cefalexin	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Potassium Canrenoate	S	Unknown	Unk Unk,Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk Unk,Unk	Sanofi
	Sulfamethoxazole/Trimethoprim	S		Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
	Oxcarbazepine	S	Unknown	Unk Unk,Unk	Not Reported
	Tramadol Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
	Zenpep	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
	Rituxan	S	Unknown	Unk Unk,Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Simponi Aria	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Unknown	Unk Unk,Unk	Not Reported
	Antivert [Meclozine Hydrochloride;Nicotinic Acid]	S	Oral	12.5 Mg,Tid	Not Reported
	Abreva	S		Unk	Not Reported
	Cyclosporine	S	Unknown	Unk Unk,Unk	Not Reported
	Cetylpyridinium Chloride;Dichlorobenzyl Alcohol;Lidocaine Hydrochlorid	S	Unknown	Unk Unk,Unk	Not Reported
	Actifed [Pseudoephedrine Hydrochloride;Triprolidine Hydrochloride]	S		Unk	Not Reported
	Vitamin D2	C	Unknown	Unk Unk,Unk	Not Reported
	Bactroban [Mupirocin]	C	Unknown	Unk Unk,Unk	Not Reported
	Citalopram Hydrobromide	C	Unknown	Unk Unk,Unk	Not Reported
	Tamiflu	C	Unknown	Unk Unk,Unk	Not Reported
	Tylenol	C	Unknown	Unk Unk,Unk	Not Reported

Singulair	C	Unknown	Unk Unk,Unk	Not Reported
Synthroid	C	Unknown	Unk Unk,Unk	Not Reported
Zoloft	C	Unknown	Unk Unk,Unk	Not Reported
Vitamins Nos	C	Unknown	Unk Unk,Unk	Not Reported
Restasis	C	Unknown	Unk Unk,Unk	Not Reported
Folic Acid	C	Unknown	Unk Unk,Unk	Not Reported
Nasocort	C	Unknown	Unk Unk,Unk	Not Reported
Advair	C	Unknown	Unk Unk,Unk	Not Reported
Prevacid	C	Unknown	Unk Unk,Unk	Not Reported
Flexeril [Cyclobenzaprine Hydrochloride]	C	Unknown	Unk Unk,Unk	Not Reported
Vicodin	C	Unknown	Unk Unk,Unk	Not Reported
Refresh [Carmellose]	C	Unknown	Unk Unk,Unk	Not Reported
Fosamax	C	Unknown	Unk Unk,Unk	Not Reported
Phenergan [Promethazine]	C	Unknown	Unk Unk,Unk	Not Reported
Tazact [Piperacillin Sodium;Tazobactam Sodium]	C	Unknown	Unk Unk,Unk	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	Unk Unk,Unk	Not Reported
Systane	C	Unknown	Unk Unk,Unk	Not Reported
Zinc	C	Unknown	Unk Unk,Unk	Not Reported
Isopto Tears [Hypromellose]	C	Unknown	Unk Unk,Unk	Not Reported
Mobic	C	Unknown	Unk Unk,Unk	Not Reported
Lamictal	C	Unknown	Unk Unk,Unk	Not Reported
Diamode	C	Unknown	Unk Unk,Unk	Not Reported
Esomeprazole	C	Unknown	Unk Unk,Unk	Not Reported
Calcium Carbonate	C	Unknown	Unk Unk,Unk	Not Reported
Zanaflex	C	Unknown	Unk Unk,Unk	Not Reported
Retin A	C	Unknown	Unk Unk,Unk	Not Reported
Vitamin D3	C	Unknown	Unk Unk,Unk	Not Reported
Hydrocortisone	C	Unknown	Unk Unk,Unk	Not Reported

Zaditor [Ketotifen]	C	Unknown	Unk Unk,Unk		Not Reported
Rubramin	C	Unknown	Unk Unk,Unk		Not Reported
Zantac	C	Unknown	Unk Unk,Unk		Not Reported
Deltasone [Dexamethasone]	C	Unknown	Unk Unk,Unk		Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown	Unk Unk,Unk		Not Reported
Protopic	C	Unknown	Unk Unk,Unk		Not Reported
Flu Vaccine Vii	C		Unk		Not Reported
Pneumococcal Vaccine	C		Unk		Not Reported
Norco	C		Unk		Not Reported
Esomeprazole Magnesium	C		Unk		Not Reported
Deltasone [Prednisone]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	13130602	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017021951		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Renal Impairment	Lyrica			S	Oral	150 Mg, Daily (3 Per Day)		Pfizer
	Lyrica			S		150 Mg, Daily		Pfizer
	Lyrica			S		50 Mg, 3x/Day (1 Capsule Three Times A Day (Tid) 90 Days)		Pfizer
	Norvasc			S		2.5 Mg, 1x/Day		Pfizer
	Prednisone			S		40 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported
	Duexis			S		Unk, 3x/Day		Not Reported
	Levothyroxine			C		125 Ug, 1x/Day		Not Reported
	Liothyronine			C		5 Ug, 3x/Day		Not Reported
	Misoprostol			C		100 Ug, 2x/Day		Not Reported
	Allegra			C		180 Mg, 1x/Day		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	13271290	EXPEDITED (15-DAY)		DS	CA-ROCHE-1898441		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	14299394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2038238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 8 Months	Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral	Extended Release	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Bupropion	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	15076418	EXPEDITED (15-DAY)		OT	CA-ROCHE-2143198		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	15327744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176025		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)					
	Mobicox			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	15493226	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022036		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Amlodipine			S	Oral	5 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Asacol			S	Oral	800 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	2.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	15713218	EXPEDITED (15-DAY)		HO, OT	US-GLENMARK PHARMACEUTICALS-2018GMK038625		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphopenia	Tacrolimus			S	Transplacental	Unk		Glenmark
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Betamethasone			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	15848950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633442-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	15935657	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657571-00		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Orencia	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	16012503	EXPEDITED (15-DAY)		DS	FR-ROCHE-2270472		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Rivotril			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported
	Skenan			S	Oral			Not Reported
	Forlax			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Salazopyrine			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Lasilix [Furosemide]			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Avodart			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	16073738	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05807		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported

	Naproxen Sodium	S	Unknown	Unknown		Not Reported
	Immunoglobulin [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)			Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	16216656	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-020662		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Ramipril			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Ramipril			S	Unknown	Unk, Once A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Every 4 Weeks		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Cosopt			S	Unknown	Unk Unk, Two Times A Day		Not Reported
	Cosopt			S	Ophthalmic	Unk Unk, Two Times A Day		Not Reported
	Cosopt			S	Ophthalmic	2 Dosage Form, Once A Day		Not Reported
	Cosopt			S	Ophthalmic	2 Dosage Form, Two Times A Day		Not Reported
	Cosopt			S	Ophthalmic	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	1 Dosage Form, Once A		Not Reported

			Day	
Levothyroxine	S	Unknown	Unk Unk, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Prednisone	S	Unknown	Unk, Once A Day	Not Reported
Remicade	S	Unknown	Unk Unk, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Altace	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once A Day	Not Reported
Levothyroxine Sodium	S	Unknown	Unk, Once A Day	Not Reported
Codeine Phosphate	S	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	1000 Milligram	Not Reported
Dorzolamide Hydrochloride;Timolol Maleate	C	Ophthalmic	Unk. Two Times A Day	Not Reported
Dorzolamide Hydrochloride;Timolol Maleate	C	Ophthalmic	2 Dosage Form, Once A Day	Not Reported
Caffeine	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Once A Day	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported

	Acetaminophen;Caffeine;Dihydrocodeine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Once A Day	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Tylenol With Codein	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Meprobamate	C	Unknown	Unk	Not Reported
	Phosphoric Acid Sodium	C	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	400 Milligram, Once A Day	Not Reported
	Timolol Maleate	C	Unknown	2 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	16296936	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK081498		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Blood Test Abnormal; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal	Salbutamol Sulphate			S		100 Ug, Prn		Glaxosmithkline
	Incruse Ellipta			S		62.5 Ug, Qd		Glaxosmithkline
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z, Monthly		Glaxosmithkline
	Ivermectin			S		Unk		Glaxosmithkline
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Prednisone			S	Oral	50 Mg, Unk		Not Reported
	Zenhale			S		2 Df, Bid, 200 Ug		Not Reported
	Pantoloc			S		40 Mg, Unk		Not Reported
	Omnaris			S		50 Ug, Unk		Not Reported

Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Alvesco	S	200 Ug, Qd	Not Reported
	Plaquenil	S	Unk	Not Reported
	Arava	C	Unk	Not Reported
	Sulfasalazine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	16481525	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-16011		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma	Infliximab			S	Oral	Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Apo-Ibuprofen			S	Oral	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported

Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Solution	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Subcutaneous	Unknown	Not Reported
Orencia	S			Not Reported
Otezla	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported

Rituxan	S	Unknown	Solution	Not Reported
Simponi	S	Subcutaneous	Unknown, Solution	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown, Solution	Not Reported
Stelara	S	Subcutaneous	Unknown	Not Reported
Sulfasalazine	S	Endocervical	Unknown	Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S			Not Reported
Benadryl	S	Unknown	Unknown	Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Colchicine	C	Unknown	Unknown	Not Reported
Colchicine	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Unknown, Delayed Release Capsule	Not Reported
Dexilant	C	Unknown	Unknown	Not Reported
Dexilant	C	Oral	Unknown, Delayed Release Capsule	Not Reported
Dexilant	C	Unknown	Unknown	Not Reported
Dexilant	C	Oral	Unknown	Not Reported
Febuxostat	C	Unknown	Unknown	Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Gravol	C	Unknown	Unknown	Not Reported

Mogadon	C	Oral			Not Reported
Mogadon	C	Oral			Not Reported
Nitrazepam	C	Unknown			Not Reported
Nitrazepam	C	Unknown			Not Reported
Nitrazepam	C	Oral			Not Reported
Oxycodone	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported
Uloric	C	Unknown			Not Reported
Uloric	C	Unknown			Not Reported
Uloric	C	Oral	Unknown		Not Reported
Uloric	C	Oral			Not Reported
Uloric	C	Unknown			Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Alendronate Sodium	C	Unknown			Not Reported
Alendronate Sodium	C	Unknown			Not Reported
Ciclosporin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	16889383	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2952012-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation;	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydrocortisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Cetirizine Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17597116	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201903-000649			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis Bacterial; Gnathoschisis; Herpes Zoster; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Valixa			S	Oral	1800 Mg, Qd		Not Reported
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prograf			S	Oral	1.5 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported

Prednisolone	S	Oral	12.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	10 Mg, Qd	Not Reported
Prednisolone	S	Oral	9 Mg, Qd	Not Reported
Prednisolone	S	Oral	8 Mg, Qd	Not Reported
Prednisolone	S	Oral	7 Mg, Qd	Not Reported
Prednisolone	S	Oral	6 Mg, Qd	Not Reported
Prednisolone	S	Oral	5 Mg, Qd	Not Reported
Bayaspirin	C		Unk	Not Reported
Rabeprazole Sodium	C		Unk	Not Reported
Rabeprazole Sodium	C			Not Reported
Halizon	C		Unk	Not Reported
Pitavastatin Calcium	C		Unk	Not Reported
Pitavastatin Calcium	C			Not Reported
Alendronate	C		Unk	Not Reported
Alendronate	C			Not Reported
Daiphen	C		Unk	Not Reported
Daiphen	C			Not Reported
Nitrazepam	C		Unk	Not Reported
Evoxac	C		Unk	Not Reported
Magnesium Oxide	C		Unk	Not Reported
Equa	C		Unk	Not Reported
Januvia	C		Unk	Not Reported
Humulin R	C		Unk	Not Reported
Aiphagan	C		Unk,Ophthalmic Solution	Not Reported
Lumigan	C		Unk	Not Reported
Timoleate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17685979	EXPEDITED (15-DAY)		HO, OT	US-ALEXION-A202005121		44 YR	Female	USA

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

Covid-19; Normocytic Anaemia; Off Label Use	Soliris 300mg		S	Intravenous (not otherwise specified)	900 Mg	Alexion
	Soliris 300mg		S	Intravenous (not otherwise specified)	900 Mg	Alexion
	Soliris 300mg		S	Intravenous (not otherwise specified)	900 Mg	Alexion
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Norepinephrine		C	Unknown	Unk	Not Reported
	Ceftriaxone		C	Unknown	2 Mg, Q12h	Not Reported
	Azithromycin		C	Unknown	Unk	Not Reported
	Rocephin		C	Unknown	Unk	Not Reported
	Propofol		C	Unknown	Unk	Not Reported
	Fentanyl		C	Unknown	Unk	Not Reported
	Midazolam		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17697018	EXPEDITED (15-DAY)		HO, OT	US-VELOXIS PHARMACEUTICALS-2018VELUS-000310			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphocytopenia Neonatal; Lymphopenia; Off Label Use; Premature Baby; Thymus Disorder	Envarsus Xr			S	Transplacental	Unk		Veloxis Pharmaceuticals
	Envarsus Xr			S				Veloxis Pharmaceuticals
	Envarsus Xr			S				Veloxis Pharmaceuticals
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported

	Steroids		S	Transplacental	Unk	Not Reported
	Betamethasone		C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17702747	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Cortisone Acetate	S	Endocervical	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous bolus	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17790411	EXPEDITED (15-DAY)		OT	NVSC2020IT130474		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Novartis
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S				Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Qd (Dsoe Tapering)		Not Reported
	Prednisone			S	Unknown	50 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd (Dose Tapering)		Not Reported

	Prednisone	S	Unknown	25 Mg, Qd (Dose Tapering)	Not Reported
	Prednisone	S	Unknown	10 Mg, Qd (Dsoe Tapering)	Not Reported
	Prednisone	S	Unknown	12.5 Mg, Qd (Dose Tapering)	Not Reported
	Tacrolimus	S	Unknown	Unk Unk, Qd	Not Reported
	Methylprednisolone	C	Unknown	Unk (Pulses)	Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Immunoglobulin I.V	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17842985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606840			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Sulfate]				
Prednisone	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Arava	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17852544	EXPEDITED (15-DAY)		DE	IT-BEH-2020117974		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	0.4 Gram Per Kilogram, Qd		Csl Behring
	Lopinavir + Ritonavir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17882738	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3435761-00		69 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Hyperbilirubinaemia	Kaletra 200/50			S	Oral	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimidos		Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Levofloxacino			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17893378	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2020ES04015			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Levofloxacin			S	Oral	500 Milligram, Qd (Per Day)		Cipla
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Bid (Every 12 Hours)		Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)	500 Milligram, Qd (Every 24 Hrs)		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Bid (Every 12 Hrs)		Not Reported
	Novorapid			C	Subcutaneous	10 International Unit, Tid (Every 8 Hours)		Not Reported
	Losartan			C	Oral	50 Milligram, Bid (Every 12 Hrs)		Not Reported
	Oseltamivir			C	Oral	75 Milligram, Qid (Every 6 Hrs)		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Milligram, In Total		Not Reported
	Piperacilina + Tazobactam			C	Intravenous (not otherwise specified)	1 Dosage Form, Tid (Every 8 Hours)		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd (Every 24 Hrs)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17893416	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported

	Losec [Omeprazole]	S	Unknown	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Metformin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17893484	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052003			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azithromycin			S	Oral	Unk		Zydus Pharm
	Kaletra			S	Oral	2 Dosage Form		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Ceftriaxon			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17893505	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported

	Nitrazadon	S	Unknown	Not Reported
	Omeprazole Magnesium	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17893645	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-028433		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure Congestive; Pulmonary Embolism	Furosemide			S	Oral	40 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported
	Enoxaparin			C	Subcutaneous	4000 International Unit, Once A Day		Not Reported
	Heparin Sodium			C	Intravenous (not otherwise specified)	Unk, Once A Day (25000 (Units Not Specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17893872	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619250		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894024	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248011		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Methotrexate			S	Unknown			Barr
	Minocycline			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894086	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894087	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248005		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C		Not Reported
	Codeine	C		Not Reported
	Darifenacin	C		Not Reported
	Desoximetasone	C		Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine	C		Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C		Not Reported
	Kenalog	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Norflex [Orphenadrine Citrtae]	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported
	Pantoprazole	C		Not Reported
	Restasis	C		Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894089	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248055			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894105	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248197		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894108	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1247509		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S	Oral	2 Dosage Forms Daily; 400 Mg Every 12 Hours		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S				Not Reported

	Bufomix Easyhaler 320 Microgramos//9 Microgramos/Inhalacion Polvo Para	C	Not Reported
	Paracetamol (12a)	C	Not Reported
	Condrosan 400 Mg Capsulas Duras	C	Not Reported
	Vesicare 5 Mg Comprimidos Recubiertos Con Pelicula	C	Not Reported
	Prednisona (886a)	C	Not Reported
	Alprazolam 2 Mg Comprimido	C	Not Reported
	Axiago 20 Mg Comprimidos Gastrorresistentes	C	Not Reported
	Atorvastatina 20 Mg Comprimido	C	Not Reported
	Lyrica 150 Mg Capsulas Duras	C	Not Reported
	Clexane	C	Not Reported
	Lorazepam 5 Mg Comprimido	C	Not Reported
	Sintrom 4 Mg Comprimidos	C	Not Reported
	Movalis 15 Mg Capsulas	C	Not Reported
	Doclis Retard 120 Mg Capsulas Duras De Liberacion Prolongada	C	Not Reported
	Rivotril 2 Mg Comprimidos	C	Not Reported
	Montelukast 10 Mg Comprimido	C	Not Reported
	Optovite B12 1.000 Microgramos Solución Inyectable	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894114	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248134		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Test Positive	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tramadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894390	EXPEDITED (15-DAY)		OT	NVSC2020IR156616		34 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Product Use In Unapproved Indication; Stillbirth	Hydroxychloroquine			S	Unknown			Novartis
	Azithromycin			S	Unknown			Not Reported
	Lopinavir + Ritonavir			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Oseltamivir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894484	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248016		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2621221		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration- 7.0 Years		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration- 6.0 Years		Not Reported
	Leflunomide			S	Unknown	Therapy Duration- 6.0 Years		Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894509	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248213		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Oestradiol Increased	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248086		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect	Methotrexate			S	Unknown			Barr

Decreased	Actemra		S	Subcutaneous		Not Reported
	Arava		S	Oral	20 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Meloxicam		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894512	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248277			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894519	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020094232		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling;	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Ml, Qwk		Not Reported
	Methotrexate Sodium			S	Intravenous (not	20 Mg, Qwk		Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Oral	20 Mg, Qd	Not Reported
	Humira		S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894536	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248022		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894539	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894541	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248060		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894546	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1248025			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894585	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248018		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Methotrexate			S	Unknown	25 Mg		Barr
	Minocycline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amoxicillin;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Bacillus Calmette Guerin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894628	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3443635-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17894950	EXPEDITED (15-DAY)		HO	ES-ACCORD-185320		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Dia		Accord
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17895003	EXPEDITED (15-DAY)		OT	IT-ROCHE-2617345		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Piperacillina/Tazobactam			C	Unknown			Not Reported
	Inhixa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17895595	EXPEDITED (15-DAY)		OT	CA-SA-2020SA152029			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Myochrysine			S	Intramuscular			Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S		25 Mg, Qw		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896283	EXPEDITED (15-DAY)		HO, OT	ES-ROCHE-2620049		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication; Thrombocytopenia	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina			S	Subcutaneous			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896537	EXPEDITED (15-DAY)		OT	OM-LUPIN PHARMACEUTICALS INC.-2020-02803		72 YR	Male	OMN

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

Off Label Use	Hydroxychloroquine	S	Unknown	Unk		Lupin
	Ceftriaxone	S	Unknown	2 Gram, Qd		Lupin
	Levofloxacin	S	Unknown	Unk		Lupin
	Azithromycin	S	Unknown	500 Milligram, Qd		Lupin
	Meropenem	C	Unknown	Unk		Not Reported
	Interferon Beta	C	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir	C	Unknown	Unk		Not Reported
	Teicoplanin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896550	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1246463			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896821	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3445517-00		64 YR	Male	ESP

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

Hepatic Enzyme Increased; Hyperbilirubinaemia	Lopinavir/Ritonavir	S	Oral	200/50mg		Not Reported
	Hidroxicloroquina	S	Oral			Not Reported
	Azitromicina	S	Oral			Not Reported
	Alopurinol	C	Oral			Not Reported
	Simvastatina	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896939	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044918		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Anakinra			S	Unknown	50 Milligram, Qd		Not Reported
	Anakinra			S	Unknown	Unk, Qwk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Qd		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Infliximab			S	Unknown	5 Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk		Not Reported
	Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			S	Oral	1.3 Milligram, Bid		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone Hexacetonide			S	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17897211	EXPEDITED (15-DAY)		OT	NVSC2020CA163552		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg (1 Every Week)		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17898864	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-18866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17898960	EXPEDITED (15-DAY)		OT	NVSC2020FR164289		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899159	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1404465			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram Daily;	Not Reported
	Desoximetasone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899165	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247894		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899167	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1465802		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899170	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248077		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899193	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1407426		57 YR	Female	CAN

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

Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Methotrexate	S	Unknown	Barr
	Nystatin	S	Unknown	Not Reported
	Nystatin	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Indometacin	C		Not Reported
	Prednisone	C		Not Reported
	Tramadol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899196	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247811		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899206	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1403565		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899256	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1248139		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S			Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ilaris Single-Use Vial	S	Unknown		Not Reported
Ilaris Single-Use Vial	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Rituximab	S	Intravenous drip		Not Reported
Rituximab	S			Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900087	DIRECT					65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Palpitations; Therapy Cessation	Hydroxychloroquine 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	12912801	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091708		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported

Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Endocervical	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Folic Acid	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
	Insulin	C	Oral	Drops Oral	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown		Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
	Metformin	C	Unknown	1 Dosage Form	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Milligram	Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	13180555	EXPEDITED (15-DAY)		OT	PHHY2017CA012940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Methotrexate			S	Subcutaneous	20 Mg, Unk		Novartis
	Neoral			S	Oral	20 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	15049785	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2141880		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Novo-Prednisone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Leflunomide	S	Oral	1.0 Df	Not Reported
Acetaminophen	C	Unknown		Not Reported
Codeine	C	Oral		Not Reported
Celebrex	C	Oral	2 Df	Not Reported
Folic Acid	C	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	C	Oral		Not Reported
Insulin	C	Oral		Not Reported
Metformin	C	Unknown	2 Df	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	15219907	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2240		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

	Humira	S	Subcutaneous	Q2wk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	15695086	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-086		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia	Azathioprine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Westward
	Hydroxychloroquine			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Betamethasone			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	15722341	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587611-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S				Not Reported
	Orencia			S	Unknown			Not Reported

Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Indometacin	C		Not Reported
	Prednisone	C		Not Reported
	Tramadol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	15802644	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616920-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	15876664	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1004861		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Teva-Prednisone			S	Unknown			Actavis
	Teva-Prednisone			S	Unknown			Actavis
	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Plaquenil			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	15928985	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007291		50 YR	Female	CAN

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

Ineffective For Unapproved Indication; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Methotrexate	S	Oral	Barr
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Zostavax	S	Unknown	Not Reported
	Zostavax	S		Not Reported
	Varicella-Zoster Immune Globulin (Human)	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	16237399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018386187		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Celebrex			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram, 1/Week		Pfizer
	Pantoprazole			S	Unknown	Unk		Unknown
	Tecta			S	Unknown	Unk		Unknown
	Xeljanz			S	Oral	50 Mg, Bid		Pfizer
	Clindamycin Hcl			S	Unknown	Unk		Pfizer
	Lopressor			S	Unknown	Unk		Not Reported
	Lopressor			S	Unknown	Unk		Not Reported

Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Biaxin Xl	S	Unknown	Unk	Not Reported
Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
Enalapril	S	Unknown	Unk	Not Reported
Enalapril	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Hctz	S	Unknown	Unk	Not Reported
Hctz	S	Unknown	Unk	Not Reported
Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Levaquin	S		Unk	Not Reported
Losartan	S	Unknown	Unk	Not Reported
Losartan	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S		Unk	Not Reported
Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Enalapril Maleate	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Losartan Potassium	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported

Plaquenil S	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Gliclazide	S	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Atenolol	C		Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Coversyl [Perindopril Erbumine]	C	Unknown	Unk	Not Reported
Leucovorin [Folinic Acid]	C	Unknown	Unk	Not Reported
Levothyroxine Sodium	C		Unk	Not Reported
Ranitidine	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Veltassa	C	Unknown	Unk	Not Reported
Venofer	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	16257462	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110611			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg		Sanofi
	Plaquenil			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S				Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sulfasalazine	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Apo-Azathioprine	S	Unknown	100 Mg		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous			Not Reported
Xeljanz	S	Unknown	5 Mg, Bid		Not Reported
Xeljanz	S				Not Reported
Bcg	C	Intravenous (not otherwise specified)			Not Reported
Amoxicillin Sodium;Clavulanate Potassium	C	Unknown			Not Reported
Leflunomide	C				Not Reported
Amoxil [Amoxicillin]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	16261220	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110517			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown	Unk Mg		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Sanofi
	Minocycline Hydrochloride			S		Unk Unk, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	16290466	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121650			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S		400 Mg, Unk		Sanofi
	Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Leflunomide			C	Unknown	Unk, Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			C		400 Mg, Unk		Not Reported
	Amoxil [Amoxicillin]			C	Unknown	Unk Unk, Unk		Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	16360160	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2798726-00			Female	CAN

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

Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Rituximab		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	16860738	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-093623		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	365.0 Units Unspecified		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17345827	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-02545		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated;	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S				Not Reported
	Actemra			S	Unknown	Unknown		Not Reported

Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Allopurinol	S	Unknown	Unknown	Not Reported
	Allopurinol	S	Unknown	Unknown	Not Reported
	Amitriptyline	S	Unknown	Unknown	Not Reported
	Amitriptyline	S	Unknown	Unknown	Not Reported
	Amitriptyline	S	Unknown	Unknown	Not Reported
	Amitriptyline Hydrochloride/Perphenazine	S	Unknown	Unknown	Not Reported
	Amitriptyline Hydrochloride/Perphenazine	S	Unknown	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Diclo	S	Unknown	Unknown, Tablet (Enteric Coated)	Not Reported
	Apo-Diclofenac	S	Topical	Unknown, Solution Topical	Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Arthrotec	S	Unknown	Unknown	Not Reported
	Arthrotec	S	Unknown	Unknown	Not Reported
	Arthrotec	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Celecoxib	S	Unknown	Unknown	Not Reported
	Celecoxib	S	Unknown	Unknown	Not Reported
	Celecoxib	S			Not Reported
	Diclofenac	S	Unknown	Unknown	Not Reported
	Diclofenac	S	Unknown	Unknown	Not Reported
	Diclofenac	S	Unknown	Unknown	Not Reported

Diclofenac Sodium	S	Unknown	Unknown	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown	Unknown	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Parenteral	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Parenteral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Misoprostol	S	Unknown	Unknown	Not Reported
Naprosyn	S	Unknown	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Nifedipine	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported

Orencia	S	Subcutaneous		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Winpred	S	Unknown	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Unknown	Unknown	Not Reported
Apo-Amitriptyline	S	Unknown	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Unknown	Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Unknown	Not Reported
Tofacitinib	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17365641	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024414			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling;	Hydroxychloroquine			S		300 Mg		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S		10 Mg		Sanofi
	Celecoxib			S		50 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Plaquenil			S		300 Mg		Sanofi

Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Prednisone	S			Not Reported
	Sulfasalazine	S		2 G	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17408807	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023723			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17518925	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564559		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17581796	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17727313	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201902-000459			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Myopathy Toxic; Neuromyopathy; Weight Decreased	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Losartan			C		100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17737108	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1229118		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Drug Interaction; Hypofibrinogenaemia; Melaena; Sepsis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; In Single Dose		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)			Not Reported

	Dexametasona (722a)		C	Intravenous (not otherwise specified)	20mg / 24h The First 5 Days, Then 10mg / 24h For 5 More Days.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17742199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229977		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17814822	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600568			Female	CAN

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

Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown	Therapy Duration: 7.0 Months	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Gabapentin	C	Oral		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17837158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605967		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Tongue Ulceration; Tooth Infection; Treatment Failure	Nystatin		S	Unknown	Not Reported
	Nystatin		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Indometacin		C	Unknown	Not Reported
	Prednisone		C		Not Reported
	Tramadol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17848404	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202005005679			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Methylprednisolone			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17856279	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535394		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Celebrex			C				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17856382	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535383		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17856406	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535379		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17856415	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535378			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Synovitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Amlodipine	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17856832	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200537327		47 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17859450	EXPEDITED (15-DAY)		HO, LT, OT	CA-JNJFOC-20200537326		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug	Remicade			S	Intravenous (not otherwise specified)			Janssen

Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17872709	EXPEDITED (15-DAY)		HO, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000470			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Bumetanide			S	Unknown	Unk		Validus
	Metoprolol Tartrate			S	Unknown	Unk		Validus
	Pentoxifylline			S	Unknown	Unk		Validus
	Diltiazem Hydrochloride			S	Unknown	Unk		Not Reported
	Capsaicin			S	Topical	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lithium Carbonate			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Memantine Hydrochloride			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Spironolactone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	13 Mg, Qd		Not Reported
	Prednisone			S	Unknown	95 Mg, Qd		Not Reported

Prednisone	S	Unknown	85 Mg, Qd	Not Reported
Montelukast	S	Unknown	Unk	Not Reported
Clonidine	S	Unknown	Unk	Not Reported
Lidocaine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Lidocaine	S	Topical	Unk	Not Reported
Cimetidine	S	Unknown	Unk	Not Reported
Ketamine	S	Topical	Unk	Not Reported
Ketamine	S	Oral	Unk	Not Reported
Ketamine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Magnesium Gluconate	S	Unknown	Unk	Not Reported
Magnesium Gluconate	S			Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Ibudilast	S	Unknown	Unk	Not Reported
Mexiletine	S	Unknown	Unk	Not Reported
N-Acetylcysteine	S	Unknown	Unk	Not Reported
Naltrexone Hydrochloride	S	Unknown	4.5 Mg, Qd	Not Reported
Palmitoylethanolamide	S	Unknown	Unk	Not Reported
Vitamin B2 /00154901/	S	Unknown	Unk	Not Reported
Vitamin B2 /00154901/	S			Not Reported
Vitamin C /00008001/	S	Unknown	Unk	Not Reported
Ezetimibe	C		Unk	Not Reported
Calcitonin	C		Unk	Not Reported
Trazodone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17878353	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005005918			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Tid		Concordia
	Zithromax			S	Oral	500 Mg, Qd		Not Reported
	Zithromax			S	Oral	250 Mg, Qd		Not Reported
	Kevzara			S	Intravenous (not otherwise specified)	400 Mg, Qd (Single Dose)		Not Reported
	Amlodipine			C				Not Reported
	Levothyrox			C				Not Reported
	Enoxaparin			C		Unk		Not Reported
	Esidrex			C		Unk		Not Reported
	Spironolactone			C		Unk		Not Reported
	Tanganil			C				Not Reported
	Salbutamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17886096	EXPEDITED (15-DAY)		OT	NVSC2020FR162122		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Tacrolimus			S	Oral	Unk		Not Reported
	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Novartis
	Plaquenil			S	Oral	Unk		Not Reported
	Pentasa			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17897547	EXPEDITED (15-DAY)		HO	CA-ROCHE-2620319		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Off Label Use; Rheumatoid Arthritis;	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Therapeutic Product Effect Decreased	Rituximab	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Meloxicam	C	Oral	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898133	EXPEDITED (15-DAY)		LT, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001196			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Hydroxychloroquine Sulfate			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2620158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown	Single Use Pre-Filled		Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Subcutaneous	Syringe	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Folic Acid	C	Oral		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898302	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-028959		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Meropenem			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day (Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898311	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1408705		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Methotrexate			S	Unknown	40 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	1 Gram Daily;	Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Unknown	30 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898313	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248019		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898316	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1401406		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898346	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1409487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Methotrexate			S	Subcutaneous			Barr

Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Methotrexate	S	Unknown		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported
	Anakinra	S			Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	6 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	.4286 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Triamcinolone	S	Intra-arterial		Not Reported
	Triamcinolone	S			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898348	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1248003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Unknown	Solution Subcutaneous		Not Reported
	Azathioprine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898373	EXPEDITED (15-DAY)		OT	CH-ROCHE-2615733		63 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Thrombosis; Blister; Dry Gangrene; Necrosis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Midazolam			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Co-Amoxicillin			S	Intravenous (not otherwise specified)			Not Reported
	Co-Amoxicillin			S				Not Reported
	Azithromycin			S	Oral			Not Reported
	Azithromycin			S				Not Reported
	Noradrenaline [Norepinephrine]			S	Intravenous (not otherwise specified)			Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported
	Propofol Lipuro			S	Intravenous (not otherwise specified)			Not Reported

	Atracurium	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898445	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1422386		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898448	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1472197		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung;	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C	Oral	11 Milligram Daily;		Not Reported

Rheumatoid Nodule	Arava	C	Unknown	20 Milligram Daily;	Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1410521			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Synovitis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898479	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248351		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

	Leflunomide		C	Unknown		Not Reported
	Xeljanz		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17898493	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006006300			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899187	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-045035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899213	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899227	NON-EXPEDITED			US-ADVANZ PHARMA-201908000279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Hydroxychloroquine			S		Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899234	EXPEDITED (15-DAY)		HO	FR-ROCHE-2619060		32 YR	Female	FRA

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

Covid-19; Covid-19 Pneumonia; Intentional Product Use Issue; Off Label Use	Rituximab		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Tocilizumab		S	Unknown	Not Reported
	Tocilizumab		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1410268		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Calcium			C		500 Milligram Daily;		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estradiol			C		1.8 Percent Daily;		Not Reported
	Estrogel			C		1.8 Percent Daily;		Not Reported
	Furosemide			C		40 Milligram Daily;		Not Reported
	Gravol			C				Not Reported
	Potassium Chloride			C		1500 Milligram Daily;		Not Reported
	Valsartan			C		320 Milligram Daily;		Not Reported
	Xalatan			C		50 Microgram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899366	NON-EXPEDITED			US-ADVANZ PHARMA-202003001546			Unknown	USA

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

Off Label Use; Pain; Product Formulation Issue; Treatment Noncompliance	Hydroxychloroquine		S	200 Mg, Bid	Concordia
	Hydroxychloroquine		S	Unk, Qd She Never Took The Product 2x Daily; She Only Took 1x Daily	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899368	NON-EXPEDITED			US-ADVANZ PHARMA-202003002110			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Erythema; Lip Swelling; Product Availability Issue; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899370	NON-EXPEDITED			US-ADVANZ PHARMA-202004004702			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Product Availability Issue; Therapy Change	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Daily		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899378	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1248344		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Cardiac Failure; Cytopenia; Generalised Oedema; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899379	NON-EXPEDITED			US-ADVANZ PHARMA-202001000066			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Tendon Pain	Hydroxychloroquine			S		Unk, Bid Tablet 200mg Tab (2x Per Day).		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899380	NON-EXPEDITED			US-ADVANZ PHARMA-201911002372			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chills; Depression; Dizziness; Drug Hypersensitivity; Feeling Abnormal; Insomnia; Malaise; Pain; Product Formulation Issue; Pyrexia; Symptom Recurrence	Hydroxychloroquine			S		200 Mg Tablet, In The Morning With Breakfast At 8 Am		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899389	NON-EXPEDITED			US-ADVANZ PHARMA-202003002115			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Reaction; Product Availability Issue; Product Substitution Issue	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899390	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric	Methotrexate			S	Unknown			Barr

Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	C		Not Reported
	Lyrica	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899392	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1471120		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899396	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201902-000292			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate			S				Concordia

(Authorized Generic),Plaquenil

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899398	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201901-000156			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899400	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201902-000200			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899403	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248184		52 YR	Female	CAN

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

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248175		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tylenol			C				Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported
	Mefenamic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899409	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201901-000002			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chapped Lips; Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Tymlos			S	Subcutaneous	80 Ug, Qd		Not Reported
	Brisdelle			C				Not Reported
	Vitamin D3			C				Not Reported

Hydroxychloroquine	C		Not Reported
Hydroxyzine	C		Not Reported
Paroxetine	C		Not Reported
Vitamin D2	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899415	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201905-001489			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Myalgia; Pain	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899417	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201905-001469			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammation; Pain; Therapeutic Response Shortened	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Daily Dose: Unknown		Concordia
	Humira			S	Subcutaneous	Strength: 40mg/0.8ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899421	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201902-000330			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899437	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001543			Unknown	USA

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

Weight Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	Unk	Concordia
	Humalog Insulin	C		6 Units Before Meal	Not Reported
	Toujeo Insulin	C		16 Units Twice Daily	Not Reported
	Aspirin	C		81 Mg, Freq: Unk X 1 Days	Not Reported
	Toprol	C		25 Mg, Freq: Unk X 1 Days	Not Reported
	Protonix	C		40 Mg, Freq: Unk X 1 Days	Not Reported
	Lyrica	C		100 Mg, Bid	Not Reported
	Lipitor	C		20 Mg, Freq: Unk X 1 Days	Not Reported
	Trulance	C		3 Mg, Freq: Unk X 1 Days	Not Reported
	Sulfasalazine	C		500 Mg, Bid	Not Reported
	Welbutrin	C		150 Mg, Tid	Not Reported
	Ambien	C		At Night	Not Reported
	Vitamin D	C		5000 Units In The Morning	Not Reported
	Vitamin B12	C		In The Morning	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899440	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001502			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899441	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001505			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899443	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001514			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Range Of Motion Decreased; Muscular Weakness; Peripheral Swelling	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899452	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001574			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899453	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001575			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Urticaria	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899454	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02874		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin

Dolutegravir;Lamivudine	C	Unknown	Unk		Not Reported
Cefepime	C	Unknown	Unk		Not Reported
Cefepime	C				Not Reported
Ampicillin	C	Unknown	Unk		Not Reported
Ampicillin	C				Not Reported
Vancomycin	C	Unknown	Unk		Not Reported
Vancomycin	C				Not Reported
Acyclovir [Aciclovir]	C	Unknown	Unk		Not Reported
Acyclovir [Aciclovir]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899464	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001555			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899497	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001587			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899499	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001609			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Inadequate Analgesia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899696	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1247807		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise; Mood Swings; Musculoskeletal Stiffness; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Indometacin			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	25 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Cymbalta			C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899777	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1400412		63 YR	Female	CAN

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

Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Synovitis	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Anakinra		S	Subcutaneous		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown	7.1429 Milligram Daily;	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899781	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1405295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899782	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899918	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1507209			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Decreased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899945	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201905-001490			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Nabumetone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899947	NON-EXPEDITED			US-ADVANZ PHARMA-202004005024			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Muscle Spasms; Nausea	Hydroxychloroquine			S	Unknown	Unk, Qd		Concordia
	Humira			S	Subcutaneous	Unk, Qd		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899948	NON-EXPEDITED			US-ADVANZ PHARMA-202003001982			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Incorrect Dose Administered; Joint Swelling; Joint Swelling; Nausea	Hydroxychloroquine			S		Every Day For 5-6 Years		Concordia
	Hydroxychloroquine			S		Unk, Dose Changed (Reduced)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899952	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001617			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899953	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001642			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899954	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001644			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Swelling; Pain	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899964	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001681			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899965	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001721			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899966	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001722			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899982	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001734			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Drug Ineffective; Malaise	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Citrate Free		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899983	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001736			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17899991	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001737			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Erythema; Hypersensitivity; Nasal Congestion; Swelling Face	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900008	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201907-001738			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900086	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1247758		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperbilirubinaemia; Long Qt Syndrome	Hidroxicloroquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Hidroxicloroquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Hidroxicloroquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S		500 Mg		Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido			S	Oral	1 Dosage Form		Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido			S	Oral	1 Dosage Form		Not Reported
	Atorvastatina [Atorvastatin]			C	Oral	20 Mg		Not Reported
	Telmisartan And Hydrochlorothiazide Tablets (80 Mg/25 Mg), Usp			C	Oral	80 Mg		Not Reported
	Metformina 850 Mg 50 Comprimidos			C	Oral	850 Mg		Not Reported
	Tocilizumab			C		600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900108	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248198		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900109	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248286			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	20 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900117	EXPEDITED (15-DAY)		HO, OT	MT-ACCORD-185146		13 YR	Male	MLT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Streptococcal; Streptococcal Sepsis; Subdural Abscess	Hydroxychloroquine			S				Accord
	Methotrexate			S				Accord
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900126	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-185319		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Off Label Use	Hydroxychloroquine			S	Oral			Accord
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248296		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Arava	C	Unknown	20 Milligram Daily;	Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1458308		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea; Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900225	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248290			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619200			Female	CAN

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

Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mirtazapine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900434	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201908-001741			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Lyrica			C	Oral	75 Mg, Freq: Unk X 1 Days		Not Reported
	Lyrica			C		Unk		Not Reported
	Primidone			C	Oral	250 Mg, Freq: Unk X 1 Days		Not Reported
	Primidone			C		Unk		Not Reported
	Levetiracetam			C	Oral	Unk Unk, Freq: Unk X 1 Days		Not Reported
	Mycophenolate			C	Oral	250 Mg, Freq: Unk X 1 Days		Not Reported
	Melatonin			C	Oral	Started About Six Months Ago		Not Reported
	Symbicort			C		Dosage: 160/4.5 120 Inhalation Two Puffs In The Morning And Night. It		Not Reported

	Escitalopram	C	Oral	Helped With Coughing. Dosage: 5mg Tablets By Mouth One At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900438	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201912002882			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Hydroxychloroquine			S		Unk, Qod (100)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900439	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201908-001821			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Memory Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900442	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201908-001746			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Increased Appetite; Sluggishness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900454	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202004002890			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900455	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000596			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900463	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201811-004023			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Bid		Concordia
	Arava			S	Oral	1 Dosage Form, Bid		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Freq: 1 X 2 Weeks		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900465	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201902-000306			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900507	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-045490		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Pain; Drug Ineffective; Gait	Orencia			S	Unknown			Bristol Myers Squibb

Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2 Every 1 Week		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tiaprofenic Acid	C	Unknown	300 Milligram, Qd		Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	81 Milligram, Qd		Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900565	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-045309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900623	NON-EXPEDITED			US-ADVANZ PHARMA-202003003127			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Heart Rate Increased	Hydroxychloroquine			S	Unknown	Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900625	NON-EXPEDITED			US-ADVANZ PHARMA-GSH201906-001540			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900740	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052038			Unknown	ESP

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

Hypertriglyceridaemia; Liver Disorder	Azithromycin		S	Oral	Unk	Zydus Pharm
	Ceftriaxon		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Kaletra		S	Oral	2 Dosage Form	Not Reported
	Hydroxychloroquine		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900741	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052059			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azithromycin			S	Oral	Unk		Zydus Pharm
	Kaletra			S	Oral	2 Dosage Form		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900742	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052039			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	Unk		Zydus Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra			S	Oral	2 Dosage Form		Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900762	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2020-GB-1247892		73 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Torsade De Pointes	Fluconazole			S	Intravenous (not otherwise specified)	(Only Received One Dose), Unit Dose: 400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	800 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901180	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020232475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Intolerance; Eye Disorder; Lung Disorder; Macular Degeneration	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901285	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1409505			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901515	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020230680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Grip Strength	Methotrexate Sodium			S	Unknown			Pfizer

Decreased; Hepatitis; Pain	Sulfasalazine	S	Unknown			Pfizer
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown	20 Mg		Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Ibuprofen	C	Unknown			Not Reported
	Imuran [Azathioprine Sodium]	C	Unknown			Not Reported
	Indomethacin [Indometacin]	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901553	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020231051			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Encephalitis; Meningitis; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901610	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE			Unknown	ESP

LIMITED-ES-ZYDUS-052037

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertriglyceridaemia; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Zydus Pharm
	Kaletra			S	Oral	2 Dosage Form, Bid		Not Reported
	Ceftriaxon			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901860	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1248348			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902003	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1480804		60 YR	Female	CAN

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

Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Methotrexate		S	Unknown	Barr
	Anakinra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902078	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248059		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902079	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247900		52 YR	Male	CAN

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

Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902080	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1248035			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902085	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248057			Female	CAN

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

Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Methotrexate		S	Unknown	Barr
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902098	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1248004		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902167	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020230769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Off Label	Enbrel			S	Unknown	50 Mg 4 Every Week		Pfizer
	Sulfasalazine			S	Oral	2000 Mg		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported

Use; Somnolence; Visual Impairment	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	20 Mg, Daily	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Meloxicam	C			Not Reported
	Methotrexate Sodium	C		25 Mg, Weekly	Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902169	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1247886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902299	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1424918			Female	CAN

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

Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17903723	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness;	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported

Rheumatoid Arthritis; Vomiting	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17903828	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1510133		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cytomegalovirus Colitis; Cytomegalovirus Gastritis; Cytomegalovirus Oesophagitis; Ulcer	Hydroxychloroquine			S	Unknown			Teva
	Hydroxychloroquine			S				Teva
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17904872	EXPEDITED (15-DAY)		OT	NVSC2020FR168278		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin Sandoz 250mg			S	Oral	Unk, Cf Commentaires		Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905337	EXPEDITED (15-DAY)		OT	NVSC2020CA164774		47 YR	Female	CAN

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

Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Malaise; Nausea; Off Label Use; Rash; Therapeutic Product Effect Decreased	Lopresor	S	Unknown		Novartis
	Clindamycin	S	Unknown		Not Reported
	Gliclazide	S	Unknown		Not Reported
	Losartan	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Tecta	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Biaxin	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Cephalexin	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enalapril	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydralazine	S	Unknown		Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Isoniazid	S	Unknown		Not Reported
	Levaquin	S	Unknown		Not Reported
	Metoprolol	S	Unknown		Not Reported
	Moxifloxacin	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Pantoprazole Magnesium	S	Unknown		Not Reported
	Pariet	S	Unknown		Not Reported
	Penicillin G	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Xeljanz	S	Oral	50 Mg, Bid	Not Reported
	Atenol	C	Unknown		Not Reported
	Colchicine	C	Unknown		Not Reported

Coversyl /Fra/	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Leucovorin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Ranitidine	C	Unknown	Not Reported
Veltassa	C	Unknown	Not Reported
Venofer	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905506	EXPEDITED (15-DAY)		OT	NVSC2020CA165481		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral			Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Rituximab			S	Endocervical			Not Reported
	Cyclosporine			S	Unknown			Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	12.5 Mg		Not Reported
	Remicade			S	Subcutaneous	3 Mg/Kg		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine	S	Oral	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17906787	EXPEDITED (15-DAY)		DE, HO	ES-ABBVIE-20K-144-3447250-00		72 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Electrocardiogram Qt Prolonged	Lopinavir/Ritonavir			S	Oral			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Amine [Amikacin Sulfate]			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17906910	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3446439-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Humira			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	9421143	EXPEDITED (15-DAY)		OT	PHHY2013FR077105		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform;	Omeprazole			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

Dna Antibody; Drug Ineffective; Erythema; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lupus Vasculitis; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Exfoliation; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	11925949	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-15K-028-1444053-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Myocardial Infarction; Near Death Experience;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Leflunomide			S	Oral			Not Reported

Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Subcutaneous	Not Reported
	Gold	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Medical Marijuana	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial	Not Reported
	Kineret	C			Not Reported
	Rituximab	C			Not Reported
	Kineret	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Rituximab W/Urelumab	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	12082828	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)	4-8mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Adequate Trial Of 3months In 2010		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 195 Days Form Of Admin Text: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Intramuscular	Therapy Duration: 6 Years		Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 6 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Asa	C	Unknown		Not Reported
Asa	C	Unknown		Not Reported
Lantus	C	Subcutaneous	Solution	Not Reported
Lozide [Indapamide]	C			Not Reported
Prednisone	C			Not Reported
Ramipril	C			Not Reported
Ergocalciferol	C			Not Reported
Vitamin D3	C			Not Reported
Xeljanz	C	Oral		Not Reported
Calcium	C			Not Reported
Metformin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	13212360	EXPEDITED (15-DAY)		OT	CA-SA-2015SA111836			Unknown	CAN

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

Abdominal Discomfort; Breast Cancer; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Plaquenil	S	Unknown	Unk Unk,Unk	Sanofi
	Arava	S	Unknown	Unk Unk,Unk	Sanofi
	Sodium Aurothiomalate	S	Intramuscular	Unk Unk,Unk	Not Reported
	Methotrexate Bellon	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
	Hydroxychloroquine	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	14169090	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210728			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	50 Mg,Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qd		Not Reported
	Actemra			S	Unknown	8 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported

	Humira		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	750 Mg,Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Meloxicam		C	Unknown		Not Reported
	Sulfasalazine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	15005310	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-068218		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Off Label Use; Respiratory Tract Infection; Therapeutic Response Decreased; Transient Hypogammaglobulinaemia Of Infancy	Mycophenolic Acid			S	Unknown	2 G, Qd		Accord
	Azathioprine			S	Unknown			Not Reported
	Prednisolone			S	Unknown	15 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisolone			S	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	15242808	EXPEDITED (15-DAY)		HO	CA-ROCHE-2163629		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Spinal Operation; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Warfarin	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Warfarin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Amitriptyline	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	15414665	EXPEDITED (15-DAY)		OT	PHHY2018NL102356		60 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Gastrointestinal Toxicity; Immunoglobulin G4 Related Disease; Off Label Use; Product Use In Unapproved Indication; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd		Novartis
	Prednisone			S				Novartis
	Prednisone			S				Novartis
	Prednisone			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	15619140	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555653-00		43 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	15622672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557461-00		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	15977831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-072428		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Simponi			S	Unknown	50 Mg, Q4wk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Tylenol Arthritis			C	Unknown	Unk, Q8h		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Unknown	10 Mg, Bid		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	16133084	EXPEDITED (15-DAY)		OT	PHHY2019CA064352		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic	Neoral			S	Unknown			Novartis
	Leflunomide			S	Unknown	20.0 Mg, Unk		Not Reported

Enzyme Increased; Liver Function Test Increased; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Methotrexate	S	Unknown	25.0 Mg, Unk	Not Reported
	Arava	S	Unknown	20.0 Mg, Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	8-Hydroxyquinoline	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prograft	S	Oral	2.0 Mg, Bid	Not Reported
	Prograft	S	Oral	3.0 Mg, Bid	Not Reported
	Prograf	S	Unknown		Not Reported
	Rapamune	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	1.0 G, Unk	Not Reported
	Tacrolimus	S	Oral	3 Mg, Bid	Not Reported
	Tacrolimus	S	Oral	2 Mg, Bid	Not Reported
	Tacrolimus	S	Unknown	3 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	16216763	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020587		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Ramipril			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram,1 Every 4 Week		Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	7 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported

Levothyroxine	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Levothyroxine	S	Unknown	Unk, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	25 Milligram, Every Week	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Cosopt	S	Unknown	Unk,1 Every 12 Hours	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Dorzolamide;Timolol	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported
Dorzolamide;Timolol	S	Unknown	Unk, Two Times A Day	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Once A Day	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
Tylenol No.2	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	16676089	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2877461-00		5 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Ciclosporin			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Imuran			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

Prednisone		C	Unknown	Not Reported
Piroxicam		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	16705133	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2884223-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17259819	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514963		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia;	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17260649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515349		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17393407	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540921			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17405028	EXPEDITED (15-DAY)		OT	CA-ROCHE-1749484		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Off Label Use; Peripheral Swelling; Rash; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17584210	EXPEDITED (15-DAY)		OT	NVSC2020CA083918		63 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral	S	Subcutaneous	Unk	Novartis
	Neoral	S	Oral	Unk	Novartis
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Cyclosporine	S	Unknown		Novartis
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg (Powder For Solution)	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid,2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17587396	EXPEDITED (15-DAY)		OT	NVSC2020CA066714		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis

Increased; Nausea; Off Label Use; Pain; Treatment Failure; Vomiting	Cyclosporine	S	Subcutaneous	Unk	Novartis
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg (Solutuion For Injection)	Not Reported
	Methotrexate	S	Unknown	Qd,1 Every 1 Day (Tablet)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	200 Mg	Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz Xr	C	Unknown		Not Reported
	Actemra	C	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17731811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Urethral	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17739591	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-021847		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram,1 Total		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17747258	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-2592551			Female	CAN

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

Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Arava	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17803596	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005298			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure Congestive	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17821771	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601274		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased;	Rituximab			S	Intravenous (not			Not Reported

Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased			otherwise specified)		
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17844833	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-025		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Prednisone			S	Transplacental			Westward
	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported

	Betamethasone	C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17850264	EXPEDITED (15-DAY)		HO, OT	CA-BAUSCH-BL-2020-015756		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Diltiazem			S	Unknown			Not Reported
	Magnesium		Y	S	Unknown			Not Reported
	Magnesium		Y	S				Not Reported
	Pentoxifylline			S	Unknown	Unspecified Dosage Form		Not Reported
	Capsaicin			S	Topical			Not Reported
	Lithium Carbonate			S	Unknown	Unspecified Dosage Form		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Bumetanid			S	Unknown			Not Reported
	Cimetidine			S	Unknown	Unspecified Dosage Form		Not Reported
	Clonidine			S	Unknown	Unspecified Dosage Form		Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibudilast			S	Unknown			Not Reported
	Ketamine			S	Topical			Not Reported
	Ketamine			S	Oral			Not Reported
	Ketamine			S	Intravenous (not otherwise specified)			Not Reported
	Lidocaine			S	Intravenous (not otherwise specified)			Not Reported
	Lidocaine			S	Topical			Not Reported
	Memantine			S	Unknown			Not Reported

Metprolol	S	Unknown			Not Reported
Mexiletine	S	Unknown			Not Reported
Montelukast	S	Unknown	Unspecified Dosage Form		Not Reported
Mycophenolate Mofetil	S	Unknown			Not Reported
N-Acetylcysteine	S	Unknown			Not Reported
Naltrexone Hydrochloride	S	Unknown			Not Reported
Palmitoylethanolamide	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Pregabalin	S	Unknown			Not Reported
Spironolactone	S	Unknown			Not Reported
Vitamin B 2	S	Unknown			Not Reported
Vitamin B 2	S				Not Reported
Vitamin C	S	Unknown			Not Reported
Calcitonin	C	Unknown			Not Reported
Ezetimib	C	Unknown			Not Reported
Trazodone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17861655	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2605562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Rituximab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Therapy Duration: 9.0 Months	Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Therapy Duration: 9.0 Months	Not Reported
	Enbrel	S	Unknown	Therapy Duration: 4.0 Years	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 4.0 Years	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Pregabalin	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Years	Not Reported
Simponi	S	Subcutaneous		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Folic Acid	C	Unknown		Not Reported
Leflunomide	C	Unknown		Not Reported
Piroxicam	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17886885	EXPEDITED (15-DAY)		OT	NVSC2020ES162135		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina			S	Oral	500 Mg, Qd		Novartis

Azitromicina	S	Oral	500 Mg, Qd		Novartis
Azitromicina	S	Oral	250 Mg, Qd		Novartis
Hydroxychloroquine	S	Oral	200 Mg, Q12h		Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Q12h		Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Qd		Not Reported
Ceftriaxona	S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
Ceftriaxona	S				Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
Tocilizumab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17892884	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3443420-00		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Cephalexin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17902397	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1455824		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Azitromicina (7019a)			S	Oral			Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17902529	EXPEDITED (15-DAY)		HO	BE-LAURUS LABS LIMITED-202000113		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemolysis; Off Label Use	Hydroxychloroquine			S	Unknown			Unknown
	Azithromycin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17902666	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009429			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Grip Strength Decreased; Hepatitis; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Ibuprofen	C	Unknown	Not Reported
	Imuran [Azathioprine Sodium]	C	Unknown	Not Reported
	Indomethacin [Indometacin]	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903087	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619622			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903209	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1455637		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertransaminasaemia	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Atorvastatina Mabo 40 Mg Comprimidos Recubiertos Con Pelicula Efg, 28			S	Oral	40 Mg		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	4 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903211	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1463398		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Sciatica	Methotrexate			S	Subcutaneous			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram Daily;		Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen/Caffeine/Dihydrocodeinebitartrate			C				Not Reported
	Acetaminophen/Codeine			C				Not Reported
	Dorzolamidehydrochloride/Timolol Maleate			C	Ophthalmic			Not Reported
	Hydroxychloroquine Sulfate			C		400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903508	NON-EXPEDITED			US-ADVANZ PHARMA-202005005960			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Zithromax			S		Unk		Not Reported

	Zinc			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903530	NON-EXPEDITED			US-ADVANZ PHARMA-202005006055			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk (Taking Ever Since She Was 2 Years Old)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903536	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202006006122			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydroxychloroquine			S				Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903544	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Topicorte	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903644	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202006006124			Unknown	USA

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

Malaise; Product Availability Issue; Product Substitution Issue	Hydroxychloroquine			S	Unknown	Unk				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903718	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202006006335			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Hydroxychloroquine			S		1 Dosage Form, Qd (1 Pill Every Day; About A Week And A Half Now)		Concordia
	Zinc			C		Unk Unk, Qd (For About A Week And A Half Now)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903736	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202006006146			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903737	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202006006343			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903747	EXPEDITED (15-DAY)		OT	PT-ACCORD-185516		84 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Hepatic Function Abnormal; Off Label Use	Hydroxychloroquine			S	Oral	200mg Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17903961	NON-EXPEDITED			US-ADVANZ PHARMA-202006006389			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17904285	NON-EXPEDITED			US-ADVANZ PHARMA-202006006400			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17904649	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-19613			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17904691	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-19532			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Infliximab			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unknown		Not Reported
	Golimumab			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Otezla			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Unknown	Unknown		Not Reported
	Advair			C	Unknown	Unknown		Not Reported
	Allopurinol			C	Unknown	Unknown		Not Reported
	Atrovent Hfa			C	Unknown	Unknown, Metered Dose (Aerosol)		Not Reported
	Codeine			C	Unknown	Unknown		Not Reported
	Cyclobenzaprine Hydrochloride			C	Unknown	Unknown		Not Reported
	Dilaudid			C	Unknown	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unknown		Not Reported

	Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
	Ibuprofen	C	Unknown	Unknown	Not Reported
	Leucovorin Calcium	C	Unknown	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Ventolin Hfa	C	Unknown	Unknown, Metered Dose (Aerosol)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905162	NON-EXPEDITED			US-ADVANZ PHARMA-202006006148			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905643	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1768304		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown	25 Mg		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Levothyroxine	C	Not Reported
	Naproxen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905806	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1772006		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905809	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788061		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Allopurinol			C				Not Reported
	Clomipramine			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

	Pantoloc [Pantoprazole]	C		Not Reported
	Zyloprim	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905811	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Glyburide			C		750 Milligram Daily;		Not Reported
	Infliximab			C				Not Reported
	Lipitor			C		10 Milligram Daily;		Not Reported
	Metformin			C	Oral			Not Reported
	Mycophenolate Mofetil			C	Oral	1500 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905814	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1787989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905875	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788088		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported

Incomplete	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C		Not Reported
	Benadryl	C		Not Reported
	Codeine	C		Not Reported
	Darifenacin	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog	C	Unknown	Not Reported
	Lasix [Furosemide]	C		Not Reported
	Loperamide	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C	Unknown	Not Reported
	Orphenadrine Citrate	C		Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Restasis	C	Unknown	Not Reported
	Rituximab	C	Intravenous drip	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905885	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788174		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17905888	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788211			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17906078	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-045911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17906153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1787872		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Hypertriglyceridaemia	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120			S	Oral	4 Dosage Forms		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17906236	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17906749	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623005		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17906782	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS-20US000213			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Torsade De Pointes	Azithromycin Usp			S	Intravenous (not otherwise specified)	500 Milligram		Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Gram, Bid		Not Reported
	Plasma			C	Intravenous (not otherwise specified)	1 Dosage Form (1 Unit)		Not Reported
	Rocephin [Ceftriaxone Sodium]			C	Intravenous (not otherwise specified)	2 Gram, Qd		Not Reported
	Heparin			C	Unknown			Not Reported
	Ephedrine			C	Intravenous (not otherwise specified)	Unk, Prn		Not Reported
	Hydrocortisone			C	Intravenous (not otherwise specified)	Unk, Prn		Not Reported
	Remdesivir			C	Intravenous (not otherwise specified)	100 Milligram, Qd		Not Reported

	Remdesivir	C	Intravenous (not otherwise specified)	200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17906848	EXPEDITED (15-DAY)		HO, OT	GB-HIKMA PHARMACEUTICALS USA INC.-GB-H14001-20-515		73 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Torsade De Pointes	Fluconazole			S	Intravenous (not otherwise specified)	(Only Received One Dose)		Hikma
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907125	EXPEDITED (15-DAY)		OT	MT-MYLANLABS-2020M1055848		13 YR	Male	MLT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Immunosuppression; Off Label Use; Product Use In Unapproved Indication	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Ibuprofen			C		Unk (Regular)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907144	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1775143		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Endocervical	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907175	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1774041		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Weight Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907344	EXPEDITED (15-DAY)		OT	NVSC2020CA165375		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Cyclosporine			S	Unknown			Novartis

	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz Xr	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907484	EXPEDITED (15-DAY)		DE	IT-MYLANLABS-2020M1055967		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]			S	Intravenous (not otherwise specified)	0.4 Gram Per Kilogram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907504	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Mobicox			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907640	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020227789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown	1500 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2x/Day		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907719	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1056032		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Off Label Use; Vomiting	Azithromycin			S	Unknown	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Mylan
	Kaletra			S	Oral	4 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907744	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020232090		48 YR	Male	ESP

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

Hepatitis	Meropenem		S	Intravenous (not otherwise specified)	Unk	Pfizer
	Amoxicillin Clavulanic Acid		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Oral	400 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907746	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020232087		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day (200 Mg/12 Hours)		Not Reported
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)	1 Df, 3x/Day (1 Df/8 Hours)		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Df, 2x/Day (2 Df/12 Hours)		Not Reported
	Atrovent			C	Respiratory (inhalation)	40 Ug, 4x/Day (40 Ug/ 6 Hours)		Not Reported
	Folic Acid			C	Oral	5 Mg/24 Hours		Not Reported
	Trimbow			C	Respiratory (inhalation)	2 Df, 2x/Day (2 Df/12 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907753	EXPEDITED (15-DAY)		OT	DE-TEVA-2020-DE-1787949		62 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Laser Surgery; Off Label Use; Retinal Tear	Hydroxychloroquin			S	Oral	600 Mg		Teva
	L-Thyroxin Hennig 75 Micro G			C	Oral	Continuous Medication, Unit Dose: 75 Microgram		Not Reported
	Lamotrigin 50 Mg			C	Oral	Continuous Medication, Unit Dose: 50 Mg		Not Reported
	Brintellix 10mg			C	Oral	Continuous Medication,		Not Reported

Unit Dose: 10 Mg

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907754	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1787871		29 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907844	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1056042		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid (12 Hours)		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400mg C/12 Horas Seguido De 200mg C/12 Horas		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907849	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1056034		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Kaletra			S	Oral	2 Dosage Form, Every 12		Mylan

Hr

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907863	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3448722-00		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous bolus	3 Bolus		Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown	(+/- 1 Mg/Kg Day)		Not Reported
	Methylprednisolone			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907882	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619775		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

	Gabapentin	C	Oral		Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907940	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3445850-00		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Kaletra 200/50			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Sulfametoxazol + Trimetoprima			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Micafungina Sodica			S	Intravenous (not otherwise specified)			Not Reported
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908235	EXPEDITED (15-DAY)		LT, OT	ES-PFIZER INC-2020232494		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported
	Rezolsta			S	Oral	1 Df, Daily		Not Reported
	Kaletra			S	Oral	2 Df, Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Daily		Not Reported
	Interferon Beta-1b			S	Subcutaneous	30 Ug, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619118		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908367	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623469			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908421	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046194		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	40 Milligram, Bid		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

Tofacitinib Citrate	S	Unknown	Unk		Not Reported
Gabapentin	C	Oral	400 Milligram, Tid		Not Reported
Tylenol Arthritis	C	Unknown	650 Milligram, Qid		Not Reported
Xeljanz	C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908474	EXPEDITED (15-DAY)		OT	NVSC2020CA165477		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	125 Mg		Novartis
	Neoral			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908476	EXPEDITED (15-DAY)		OT	NVSC2020CA165392		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported

Ciclosporin	S	Unknown	Unk		Novartis
Leflunomide	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q4w		Not Reported
Humira	S	Unknown			Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908845	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3447164-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Penicillin G			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Tylenol	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908885	EXPEDITED (15-DAY)		OT	NVSC2020CA165383		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Rituximab			S	Endocervical	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q4w		Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Simponi	S	Subcutaneous	3 Mg/Kg	Not Reported
	Xeljanz	C	Oral	2 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909040	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3448408-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Body Height Below Normal; Human Antichimeric Antibody Positive; Joint Destruction; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	Human		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909073	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1057037			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909075	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1057038			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Mylan
	Rituximab			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909286	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-045913		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Unknown			Not Reported
Rituximab	S	Intravenous drip	1000 Milligram		Not Reported
Arava	C	Unknown			Not Reported
Calcium Carbonate	C	Unknown			Not Reported
Cymbalta	C	Unknown			Not Reported
Elavil [Allopurinol]	C	Unknown			Not Reported
Hydrochlorothiazide	C	Unknown			Not Reported
Imitrex [Sumatriptan]	C	Unknown			Not Reported
Lyrica	C	Unknown			Not Reported
Premarin	C	Unknown			Not Reported
Sumatriptan	C	Unknown			Not Reported
Tenormin	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909352	EXPEDITED (15-DAY)		HO	NVSC2020FR168959		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Novartis
	Plaquenil			S	Oral			Not Reported
	Lovenox			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909617	EXPEDITED (15-DAY)		HO	NVSC2020ES169411		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina			S	Oral	500 Mg, Qd		Novartis
	Amoxicillin, Clavulanic Acid			S	Oral	1 Df, Q8h		Not Reported
	Tocilizumab			S	Intravenous (not	600 Mg, Qd		Not Reported

					otherwise specified)					
	Dolquine			S	Oral	200 Mg, Q12h				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909833	EXPEDITED (15-DAY)		OT	NVSC2020CA165312		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Unknown	Unk (Solution Subcutaneous)		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Remicade			S	Intraocular	3.0 Mg/Kg (Powder For Solution Intravenous)		Not Reported

	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17909985	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA169540			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910108	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-19531		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective	Etanercept			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Amlodipine Besilate			C	Unknown	Unknown		Not Reported
	Desoximetasone			C	Topical	Unknown		Not Reported
	Diclofenac			C	Topical	Unknown		Not Reported
	Naproxen			C	Unknown	Unknown		Not Reported
	Stelara			C	Unknown	Unknown, Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910230	EXPEDITED (15-DAY)		DE, HO, LT	NVSC2020CA168461			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported

Anakinra	S	Unknown	Unk		Not Reported
Anakinra	S				Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Enbrel	S				Not Reported
Humira	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	12262173	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1600077-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Drug Ineffective; Joint Stiffness; Joint Swelling; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin			S	Unknown			Not Reported

Actemra	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Gold (198 Au)	S	Unknown	Not Reported
Indocid	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Methotrexate Sodium	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Cymbalta	C	Oral	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	14357018	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA268182			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Contusion; Disability; Drug Ineffective; Fatigue; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling; Swelling	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	15377600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184324		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Actemra			S	Unknown	Therapy Duration: 365.0		Not Reported
	Actemra			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 366.0		Not Reported
	Rituxan			S				Not Reported
	Arava			S	Oral	Therapy Duration: 365.0		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 366.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 16.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 638.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 8.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 396.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	15384083	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082847		64 YR	Female	CAN

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

Dysphonia; Dyspnoea; Intentional Product Use Issue; Odynophagia; Rheumatoid Arthritis; Stridor	Orencia	S	Unknown	Unk		Bristol Myers Squibb
	Golimumab	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	15625609	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2557423-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Apo-Cyclosporine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Motrin	S	Oral	Not Reported
	Motrin	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Cyclosporine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Ibuprofen	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Folic Acid	C			Not Reported
Nitrazepam	C	Oral		Not Reported
Oxycodone	C			Not Reported
Uloric	C			Not Reported
Prednisone	C			Not Reported
Xeljanz	C			Not Reported
Benadryl	C			Not Reported
Dexilant	C	Oral		Not Reported
Febuxostat	C			Not Reported
Gravol	C			Not Reported
Mogadon	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	15635108	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556219-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Dysphonia; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Apo-Warfarin			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	15801087	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617003-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	Unit Dose- Dosage Forms		Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leucovorin			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral			Not Reported
Leflunomide	S	Oral			Not Reported
Prednisone	S	Unknown	2 Dosage Forms		Not Reported
Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	15855790	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633737-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	16003883	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2678572-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous	Humira			S	Subcutaneous			Not Reported

Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Methotrexate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	16182582	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2738227-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Rheumatoid Arthritis; Sciatica; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Subcutaneous			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Codeine Phosphate	S	Unknown	Not Reported
	Cosopt	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Levothyroxine Sodium	S	Unknown	Not Reported
	Altace	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen W/Codeine Phosphate	C	Intravenous (not otherwise specified)	Not Reported
	Tylenol No.2	C	Unknown	Not Reported
	Acetaminophen W/Caffeine	C	Unknown	Not Reported
	Plaquenil	C		Not Reported
	Acetaminophen/Caffeine/Codeine Phosphate	C		Not Reported
	Caffeine W/Dihydrocodeine Bitartrate/Paraceta	C		Not Reported
	Caffeine	C		Not Reported
	Dorzolamide Hydrochloride/Timololmaleate	C	Ophthalmic	Not Reported
	Methylprednisolone	C		Not Reported
	Paracetamol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	16348587	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2793228-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Sulfasalazine	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Penicillin G	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Actemra	S	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported
Prednisone	C		Not Reported
Hydroxychloroquine	C		Not Reported
Tylenol	C		Not Reported
Calcium	C		Not Reported
Vitamin D	C		Not Reported
Plaquenil	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	16607608	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040844		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Cephalexin Tablets			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Clindamycin			S	Unknown	Unk		Aurobindo
	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Losartan Tablets			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Avelox			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported

	Enalapril	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G	S	Unknown	Unk	Not Reported
	Penicillin Nos	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Venofer	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	16617646	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190717471		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Decreased; C-Reactive Protein Increased; Chills; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Joint Swelling; Liver Disorder; Loss Of Personal Independence In Daily Activities; Mesenteritis; Musculoskeletal Stiffness; Nausea; Oedema Peripheral; Off Label Use; Panniculitis; Peripheral Swelling; Pyrexia; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Leflunomide	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported

	Alendronic Acid		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported
	Ciclosporin		C	Unknown	Not Reported
	Alendronate Sodium		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	16702827	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888402-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous	Form Of Administration-Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported

Erythematosus; Treatment Failure; Wound	Reactine (Cetirizine Hydrochloride)	S			Not Reported
	Arava	S	Oral		Not Reported
	Methotrexate	S	Oral	2.5 Milligram	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S			Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Actemra	S	Oral		Not Reported
	Actemra	S	Topical		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Plaquenil	S	Oral	1.0 Unit	Not Reported
	Topicort	S	Topical	Cream	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported

Diclofenac	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cortisone	S	Unknown	Not Reported
Cortisone	S	Oral	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Golimumab	S	Unknown	Not Reported
Nhydrocortisone Acetate	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Salazopyrin	C		Not Reported
Tofacitinib Citrate	C		Not Reported
Apo-Prednisone	C		Not Reported
Atasol [Paracetamol]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17024666	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459897			Female	CAN

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

Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17396502	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported

Folic Acid	S	Unknown	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Diclofenac	S	Unknown			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Diclofenac Sodium	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Etanercept	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17400078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540883		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Type 1	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Diabetes Mellitus; Vomiting	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17411839	EXPEDITED (15-DAY)		DS	CA-ROCHE-2546716		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Gold	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S		Not Reported
Bifidobacterium Bifidum	C		Not Reported
Celebrex	C		Not Reported
Loperamide	C		Not Reported
Pantoprazole	C		Not Reported
Xeljanz	C		Not Reported
Arava	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17562971	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022558		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17629213	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002163			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17729176	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228816		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Infusion	Diclofenac Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Paracetamol			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Apo Prednison	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil /00072602/	S	Unknown	400 Milligram Daily;	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Subcutaneous		Not Reported
Salazopyrine	S	Unknown	2 Gram Daily;	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Topicort Lp	S	Subcutaneous		Not Reported
Topicort Lp	S	Oral		Not Reported
Winpred	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17754228	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180840374			Female	CAN

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

Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Tenosynovitis; Urticaria; Wrist Surgery	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfamethoxazole/Tri Methoprim	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17757979	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200500971		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Thrombosis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17758024	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17763317	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2594978		33 YR	Female	CAN

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

Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Celexa [Citalopram Hydrobromide]	C	Unknown	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Losec [Omeprazole]	C		Not Reported
	Naprosyn [Naproxen]	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Crestor	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17763811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Gait Inability; Joint Swelling; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17765937	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748865		65 YR	Female	CAN

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

Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Risedronate	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Naproxen	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17781433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593776			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily	Actemra			S	Unknown	335 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel		S		Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate		S	Unknown	Not Reported
	Cimzia		S	Unknown	Not Reported
	Cimzia		S		Not Reported
	Leflunomide		C	Unknown	Not Reported
	Sulfasalazine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17788220	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2598905		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S		Not Reported
Ilaris	S	Unknown	Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Cannabis Sativa	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S		Not Reported
Oxycodone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17810842	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600284		59 YR	Male	CAN

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

Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Pantoprazole	C	Oral	Not Reported
	Pantoprazole Sodium Anhydrous	C		Not Reported
	Pantoprazole Sodium Sesquihydrate	C		Not Reported
	Tenofovir	C		Not Reported
	Tenofovir Disoproxil	C		Not Reported
	Tenofovir Disoproxil Fumarate	C		Not Reported
	Tenofovir Disoproxil Fumarate	C		Not Reported
	Xeljanz	C		Not Reported

	Zopiclone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17813252	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020198921		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Feeling Hot; Flushing; Senile Pruritus; Skin Exfoliation; Skin Reaction	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Rezolsta			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17814986	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-025966		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17821134	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005422			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome; Off Label Use; Ventricular Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	400 Mg, Bid		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17828576	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605551			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Actemra			S	Unknown	122.0 Days		Not Reported
	Rituximab			S	Unknown	45.0 Days		Not Reported
	Arava			S	Unknown	61.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	366.0 Days		Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17837483	EXPEDITED (15-DAY)		DS, HO	CA-JNJFOC-20200526841		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Ibuprofen			S	Oral			Johnson And Johnson
	Ibuprofen			S	Oral			Johnson And Johnson
	Ibuprofen			S	Oral			Johnson And Johnson
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported

Musculoskeletal Stiffness; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Tongue Disorder; Ulcer	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Infliximab	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not	Not Reported

		otherwise specified)	
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Colchicine	C	Oral	Not Reported
Dexilant	C	Unknown	Not Reported
Febuxostat	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported
Nitrazepam	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Uloric	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17849105	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17850265	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity;	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17857817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Advil [Ibuprofen]	C			Not Reported
	Mefenamic Acid	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Dequalinium Chloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17858036	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005961			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonia	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17859384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187404		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Humira	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Subcutaneous	Not Reported
Cyclosporin	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Arava	C	Oral	Not Reported
Risedronate	C	Oral	Not Reported
Risedronate	C	Oral	Not Reported
Cimzia	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17863809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use;	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17899759	EXPEDITED (15-DAY)		OT	NVSC2020CA165350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Unknown			Not Reported

	Orencia	S	Subcutaneous	125 Mg		Not Reported
	Remicade	S	Unknown	3 Mg		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17899762	EXPEDITED (15-DAY)		OT	NVSC2020CA165360		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Oral			Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin Sandoz			S	Unknown			Novartis
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17909556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Rituximab			S	Intravenous (not otherwise specified)	403.0 Days		Not Reported
	Adalimumab			S	Subcutaneous	8.0 Years		Not Reported
	Imuran [Azathioprine]			S	Unknown	21.0 Years		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	6.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Glyburide			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Mycophenolate Mofetil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17909567	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020230217		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use; Product Use In Unapproved Indication; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, 2x/Day		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17909569	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020230215		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day (Every 24 Hours)		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Lopinavir And Ritonavir			S	Oral	400 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Lopinavir And Ritonavir			S				Not Reported
	Bufomix Easyhaler			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Condrosan			C		Unk		Not Reported
	Vesicare			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Axiago			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Clexane			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Sintrom			C		Unk		Not Reported
	Movalis			C		Unk		Not Reported
	Doclis			C		Unk		Not Reported
	Rivotril			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Optovite B12			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17909820	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES-1788338		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Interferon Beta-1b (2305od)			S	Subcutaneous	30 Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17909974	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-030041		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17909983	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-029785		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Mixed Liver Injury	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tacrolimus			S	Oral	8 Milligram, Once A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Milligram, Once A Day		Not Reported

	Prednisone	S	Oral	20 Milligram, Once A Day	Not Reported
	Metoclopramide	S	Intravenous (not otherwise specified)	10 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910016	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Encephalitis; Meningitis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910233	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-045461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910429	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619988			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910467	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-029784		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Co-Trimoxazole			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Micafungin Sodium			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910535	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Intolerance; Eye Disorder; Lung Disorder; Macular Degeneration	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910551	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910816	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910836	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Flank Pain; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased; White Blood Cell Disorder	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910914	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1788047		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	200 Mg		Teva
	Amoxicilina/Acido Clavulanico			S	Intravenous (not	1 Dosage Form		Not Reported

	1.000 Mg/200 Mg Inyectable		otherwise specified)		
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido	S	Oral	2 Dosage Forms	Not Reported
	Atrovent 20 Microgramos Solucion Para Inhalacion En Envase A Presion,	C	Respiratory (inhalation)	40 Mcg	Not Reported
	Acido Folico 5 Mg 28 Comprimidos	C	Oral	5 Mg	Not Reported
	Trimbow 87 Microgramos/5 Microgramos/9 Microgramos Solucion Para Inhal	C	Respiratory (inhalation)	2 Dosage Forms	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910921	EXPEDITED (15-DAY)		LT	NVSC2020CA169291			Male	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910951	EXPEDITED (15-DAY)		HO, LT	NVSC2020ES169448		62 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Long Qt Syndrome	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd (2 Gr Dia)		Novartis
	Ceftriaxone			S				Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500mg Dia)		Not Reported
	Azithromycin			S				Not Reported
	Dolquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911060	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-250138			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Pulmonary Haemorrhage Neonatal	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Aspirin			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Noradrenaline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911062	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL		39 YR	Female	USA

INDUSTRIES LTD-
2020R1-250136

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Drug Ineffective; Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Sun
	Azithromycin			S	Unknown	Unk		Sun
	Aspirin			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Noradrenaline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911066	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-250137			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Aspirin			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Noradrenaline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911068	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911074	EXPEDITED (15-DAY)		DE	ES-ALVOGEN-2020-ALVOGEN-108590		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Coma; Hypotension; Tachycardia	Nitroglycerin			S	Topical			Not Reported
	Metamizole Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Piperacillin Sodium/Tazobactam Sodium			C	Intravenous (not otherwise specified)			Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911128	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Encephalitis; Meningitis; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported

Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Unknown	2 Months		Not Reported
Prednisone	S	Unknown			Not Reported
Remicade	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911257	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2664692-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911424	EXPEDITED (15-DAY)		OT	CA-ACCORD-185743		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cetirizine		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Desoximetasone		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S			Not Reported
	Plaquenil		S	Unknown	1 Every 1 Days	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	2 Every 1 Days	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911425	EXPEDITED (15-DAY)		HO	ES-ACCORD-185545		76 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg (1-0-0,5)		Not Reported
	Imurel			S	Oral	Strength: 50 Mg, 50 Tablets, 1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911469	EXPEDITED (15-DAY)		LT	NVSC2020FR168995		78 YR	Male	FRA

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

Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone	S	Oral	2 Mg, Qd	Novartis
	Plaquenil	S	Oral	600 Mg, Qd	Not Reported
	Effexor	S	Oral	150 Mg, Qd	Not Reported
	Acebutolol Hydrochloride	C	Oral	400 Mg, Qd	Not Reported
	Oxazepam	C	Oral	100 Mg, Qd	Not Reported
	Enoxaparine Sodique	C	Subcutaneous	4000 Iu, Qd	Not Reported
	Macrogol 4000	C	Oral	2 Df, Qd	Not Reported
	Amlodipine	C	Oral	10 Mg, Qd	Not Reported
	Clomipramine Hydrochloride	C	Oral	150 Mg, Qmo	Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd	Not Reported
	Nicardipine Hydrochloride	C	Oral	60 Mg, Qd	Not Reported
	Hydrochlorothiazide	C	Oral	25 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623595		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Off Label Use; Rash; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

	Simponi	C	Subcutaneous	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911830	EXPEDITED (15-DAY)		OT	NVSC2020BR080846		65 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Hypermetropia	Cosentyx			S	Unknown	300 Mg		Novartis
	Cosentyx			S	Subcutaneous	150 Mg, Qmo(2 Ampoules)		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd(Before Cosentyx)		Not Reported
	Methotrexate			C	Oral	2.5 Mg(5 Tablets Once A Week, Started Before Cosentyx)		Not Reported
	Calcium			C	Oral	600 Mg(One Tablet Of 600 Mg Twice Daily)		Not Reported
	Vitamin D			C	Oral	400 Mg(One Tablet Of 400 Mg Twice Daily)		Not Reported
	Omeprazole			C	Oral	20 Mg, Qd(Since 20 Years Old)		Not Reported
	Alendronate Sodium			C	Oral	70 Mg, Qw		Not Reported
	Diosmina Hesperidina			C	Oral	Unk(2 Tablets Of 450 Mg Of Diosminand 50 Mg Of Hesperidina Per Day)		Not Reported
	Folic Acid			C	Oral	5 Mg(2 Tablets Of 5 Mg Once A Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911887	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1788203		61 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Liver	Hydroxychloroquine			S	Oral	200mg 12 / 12h, Unit		Teva

Injury; Rash

	Norepinephrine	C	Dose: 400 Mg	Not Reported
	Morphine	C		Not Reported
	Lopinavir, Ritonavir	C		Not Reported
	Paracetamol	C		Not Reported
	Midazolam	C		Not Reported
	Propofol	C		Not Reported
	Enoxaparin Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911939	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624447		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17911986	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution		Not Reported

						Intravenous				
	Rituximab			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912060	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA169369			Male	CAN

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

	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912068	EXPEDITED (15-DAY)		LT	NVSC2020CA169469			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported

	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912136	EXPEDITED (15-DAY)		HO	ES-ACCORD-185575		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912156	EXPEDITED (15-DAY)		HO	NVSC2020FR162460		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Azithromycin Sandoz			S	Oral	Unk		Novartis
	Plaquenil			S	Oral	Unk		Not Reported
	Cardensiel			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623724		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

			otherwise specified) Intravenous		
	Xeljanz	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912519	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2621036		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912630	EXPEDITED (15-DAY)		HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001846			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine Sulfate			S	Oral	800 Milligram, Qd		Ipca
	Lansoprazole			C	Unknown	Unk		Not Reported
	Cassia			C	Unknown	Unk		Not Reported
	Glyceryl Trinitrate Solution			C	Unknown	Unk		Not Reported
	Apixaban			C	Unknown	Unk		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912646	EXPEDITED (15-DAY)		HO	CA-CIPHER-2020-CA-000810		78 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Tramadol Hydrochloride			S	Unknown	Unknown Dose		Cipher
	Diclofenac Potassium			S	Unknown	Unknown Dose		Not Reported
	Enbrel			S	Unknown	Unknown Dose		Not Reported
	Gold			S	Unknown	Unknown Dose		Not Reported
	Humira			S	Unknown	Unknown Dose		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown Dose		Not Reported
	Ibuprofen			S	Unknown	Unknown Dose		Not Reported
	Methotrexate			S	Unknown	Unknown Dose		Not Reported
	Motrin			S	Unknown	Unknown Dose		Not Reported
	Naprosyn			S	Unknown	Unknown Dose		Not Reported
	Acetylsalicylic Acid (Aspirin)			S	Unknown	Unknown Dose		Not Reported
	Naproxen			S	Unknown	Unknown Dose		Not Reported
	Plaquenil			S	Oral	Unknown Dose		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown Dose		Not Reported
	Sulfamethoxazole			S	Unknown	Unknown Dose		Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unknown Dose		Not Reported
	Sulfatrim			S	Unknown	Unknown Dose		Not Reported
	Trimethoprim			S	Unknown	Unknown Dose		Not Reported
	Vitamin C			S	Unknown	Unknown Dose		Not Reported
	Voltaren			S	Unknown	Unknown Dose		Not Reported
	Naproxen Sodium			S	Unknown	Unknown Dose		Not Reported
	Acetylsalicylic Acid / Clopidogrel			S	Unknown	Unknown Dose		Not Reported
	Asa			S	Unknown	Unknown Dose		Not Reported
	Gold			S	Unknown	Unknown Dose		Not Reported
	Apo-Diclofenac			S	Topical	Unknown Dose		Not Reported
	Apo-Sulfatrim			S	Unknown	Unknown Dose		Not Reported
	Arava			S	Unknown	Unknown Dose		Not Reported

Clopidogrel	S	Unknown	Unknown Dose		Not Reported
Diclofenac	S	Unknown	Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912749	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020232026		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatitis; Hypertriglyceridaemia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Every 12 Hours		Not Reported
	Kaletra			S	Oral	500 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912755	EXPEDITED (15-DAY)		LT	ES-PFIZER INC-2020232120		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day		Not Reported
	Rezolsta			S	Oral	1 Df, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Kaletra			C	Oral	2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912906	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA169340			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep	Ilaris			S	Subcutaneous	Unk		Novartis

Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris	S				Novartis
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S				Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Actemra	S				Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Anakinra	S				Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S				Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S				Not Reported
	Sulfasalazine	S	Unknown	500 Mg		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912977	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1778055		74 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Covid-19 Treatment	Hydroxychloroquine			S	Oral	200mg 3xs / Week Post Hemodialysis, 600 Mg		Teva
	Bisoprolol			C				Not Reported

	Omeprazole	C	Not Reported
	Clonazepam	C	Not Reported
	Acetylsalicylic Acid	C	Not Reported
	Sevelamer	C	Not Reported
	Simvastatin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913067	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1788097		51 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913083	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1757862			Male	CAN

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

Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913088	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1773984		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913166	EXPEDITED (15-DAY)		DE	NVSC2020ES169588		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913170	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1056270		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Off Label Use	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Azithromycin			S		Unk		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	200 Milligram, Bid		Mylan
	Amoxicilina + Acido Clavulonico			S	Intravenous (not otherwise specified)	1 Dosage Form, Q8h		Mylan
	Atrovent			C	Respiratory (inhalation)	40 Microgram, Q6h		Mylan
	Acido Folico /00024201/			C	Oral	5 Milligram, Qd		Mylan
	Trimbow			C	Respiratory (inhalation)	2 Dosage Form, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913173	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1056287		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatitis;	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported

Hypertriglyceridaemia; Off Label Use	Ceftriaxona /00672201/	S	Intravenous (not otherwise specified)	1 Gram, Qd	Mylan
	Hidroxicloroquina Sulfato	S	Oral	400 Milligram, Qd	Mylan
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Milligram, Bid	Mylan
	Kaletra	S	Oral	2 Dosage Form, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913474	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1788337		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatitis; Hypertriglyceridaemia	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913524	EXPEDITED (15-DAY)		HO, OT	US-SAKK-2019SA144317AA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Asthenia; Back Pain; Blister; Constipation; Contusion; Diarrhoea; Drug Hypersensitivity; Drug Intolerance;	Arava			S	Unknown	Unk		Sanofi
	Alprazolam			S	Unknown	0.5 Mg, Tid		Not Reported
	Isosorbide Dinitrate			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Sanofi
	Ampicillin			S	Unknown			Not Reported
	Pregabalin			S	Oral	100 Mg, Qd		Not Reported

Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Oedema; Oral Pain; Osteoarthritis; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing; Wound	Cetirizine Hydrochloride	S	Unknown	10 Mg, Qd	Not Reported
	Ziprasidone Hydrochloride	S	Unknown		Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown		Not Reported
	Colchicine	S	Unknown	Unk	Not Reported
	Prochlorperazine	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Diamox	S	Unknown		Not Reported
	Doxycycline	S	Unknown		Not Reported
	Hydrochlorothiazide/Triamterene	S	Unknown		Not Reported
	Erythromycin	S	Unknown		Sanofi
	Iron (Salt Not Specified)	S	Unknown		Not Reported
	Cefalexin	S	Unknown	Unk	Not Reported
	Lasix	S	Unknown		Sanofi
	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Sanofi
	Potassium	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Sanofi
	Sulfasalazine	S	Unknown		Not Reported
	Oxcarbazepine	S	Unknown		Not Reported
	Tramadol Hydrochloride	S	Unknown		Not Reported
	Mesalazine	S	Unknown		Sanofi
	Sulfamethoxazole/Trimethoprim	S	Unknown		Not Reported
	Citalopram Hydrobromide	S	Unknown	Unk	Not Reported
	Flagyl	S	Unknown		Sanofi
	Vitamin D2	C	Unknown		Not Reported
	Bactroban [Mupirocin]	C		Unk	Not Reported
	Tamiflu	C	Unknown		Not Reported
	Tylenol [Paracetamol]	C			Not Reported
	Singulair	C		Unk	Not Reported

Synthroid	C	Unknown		Not Reported
Zoloft	C			Not Reported
Mvi [Vitamins Nos]	C			Not Reported
Restasis	C			Not Reported
Folic Acid	C			Not Reported
Nasocort	C			Not Reported
Advair	C			Not Reported
Prevacid	C			Not Reported
Flexeril [Cyclobenzaprine Hydrochloride]	C			Not Reported
Vicodin	C			Not Reported
Refresh [Carmellose]	C			Not Reported
Fosamax	C			Not Reported
Phenergan [Promethazine]	C		Unk	Not Reported
Tazact [Piperacillin Sodium;Tazobactam Sodium]	C	Unknown		Not Reported
Vitamin D [Ergocalciferol]	C	Unknown		Not Reported
Systane	C	Unknown		Not Reported
Isopto Tears [Hypromellose]	C			Not Reported
Mobic	C			Not Reported
Lamictal	C			Not Reported
Diamode	C			Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown		Not Reported
Calcium Carbonate	C			Not Reported
Zanaflex	C			Not Reported
Retin A	C			Not Reported
Flu Vaccine Vii	C		Unk	Not Reported
Pneumococcal Vaccine	C	Unknown	Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Norco	C		Unk	Not Reported
Hydrocortisone	C			Not Reported
Zinc	C			Not Reported
Zaditor [Ketotifen]	C			Not Reported
Rubramin	C			Not Reported
Zantac	C		Unk	Not Reported
Deltasone [Prednisolone]	C			Not Reported
Vitamin B12 [Cyanocobalamin]	C			Not Reported

	Protopic			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913548	EXPEDITED (15-DAY)		DE	NVSC2020IT169202		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913639	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1057410		49 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Off Label Use; Transaminases Increased	Lopinavir/Ritonavir Mylan			S	Oral	2cp 12/12h		Mylan
	Plaquinol			S	Oral	400mg 12/12h No D1; 200mg 12/12h Nos Dias Seguintes		Mylan
	Enoxaparin Sodium			C		Unk		Mylan
	Furosemide			C		Unk		Mylan
	Bromazepam			C	Oral	Unk		Mylan
	Propofol			C	Intravenous (not otherwise specified)	Unk		Mylan
	Bisoprolol			C	Oral	Unk		Mylan
	Amoxicilina + Acido Clavulanico			C		Unk		Mylan
	Amiodarone			C		Unk		Mylan
	Acetylcysteine			C		Unk		Mylan
	Esomeprazole			C		Unk		Mylan
	Rocuronium Bromide			C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913703	EXPEDITED (15-DAY)		OT	NVSC2020ES168328		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine			S				Novartis
	Linezolid			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ambisome			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk (Desconocida)		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913885	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624296		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913959	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020235474		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Toxic Skin Eruption	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914164	EXPEDITED (15-DAY)		LT	NVSC2020FR169790		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914192	EXPEDITED (15-DAY)		HO	NVSC2020US170540			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	600 Mg, Bid		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914553	EXPEDITED (15-DAY)		OT	NVSC2020ES169608		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg/24h)		Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500 Mg/24h)		Not Reported
	Azithromycin			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Once/Single (600mg Dosis Unica)		Not Reported
	Tocilizumab			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk (2gr/24h)		Not Reported
	Ceftriaxona			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914555	EXPEDITED (15-DAY)		DE	NVSC2020ES169800		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Q12h		Novartis
	Quetiapine			S	Oral	25 Mg, Qd		Not Reported
	Levofloxacin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Risperidona			S	Oral	1 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Qd		Not Reported
	Clindamycini Hydrochloridum			C	Intravenous (not otherwise specified)	600 Mg, Q6h		Not Reported
	Lorazepam			C	Oral	1 Mg, Qd		Not Reported
	Losartan			C	Oral	50 Mg, Qd		Not Reported
	Furosemide			C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914618	EXPEDITED (15-DAY)		HO	NVSC2020ES169556		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported
	Dolquine			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914620	EXPEDITED (15-DAY)		OT	NVSC2020ES169605		30 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg/24h)		Novartis

	Hydroxychloroquine	S				Novartis
	Azithromycin	S	Oral	500 Mg, Qd (500 Mg/24h)		Not Reported
	Ceftriaxona	S	Intravenous (not otherwise specified)	2 G, Qd (2gr/24h)		Not Reported
	Ceftriaxona	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914621	EXPEDITED (15-DAY)		HO	NVSC2020ES169603		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Not Reported
	Azithromycin			S				Not Reported
	Amoxicillin Sodium,Potassium Clavulanate			S	Intravenous (not otherwise specified)	1 Df, Q8h (Cada 8 Horas)		Novartis
	Amoxicillin Sodium,Potassium Clavulanate			S				Novartis
	Dolquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Not Reported
	Dolquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Qd (600 Mg Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914622	EXPEDITED (15-DAY)		HO	NVSC2020ES169478		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Propofol Infusion Syndrome	Propofol 20 Mg/Ml (2%) Emulsion For Injection/Infusion			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azitromicina			S	Oral	500 Mg, Qd		Novartis
	Azitromicina			S				Novartis
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Dolquine			S				Not Reported
	Dexametasona			C	Intravenous (not otherwise specified)	4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914626	EXPEDITED (15-DAY)		HO	NVSC2020ES169611		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azithromycin			S	Oral	500 Mg, Qd (Dia)		Novartis
	Azithromycin			S				Novartis
	Kaletra			S	Oral	2 Df, Q12h (2 U/12h)		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Mg, Qd (Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914773	EXPEDITED (15-DAY)		OT	NVSC2020PL080485		74 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dyspnoea; Nausea; Vomiting	Leflunomide			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Novartis
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Plaquenil			S	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914797	EXPEDITED (15-DAY)		HO	NVSC2020ES169835		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azitromicina			S	Oral	500 Mg, Qd (500 Mg Dia)		Novartis
	Azitromicina			S				Novartis
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd (2 G Dia)		Not Reported
	Ceftriaxona			S				Not Reported
	Dolquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914822	EXPEDITED (15-DAY)		OT	NVSC2020ES169680		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Q12h		Novartis
	Hydroxychloroquine Sulfate			S				Novartis
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported
	Azitromicina			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914833	EXPEDITED (15-DAY)		HO	NVSC2020ES169371		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Interferon Beta-1b			S	Subcutaneous	0.25 Mg		Novartis
	Interferon Beta-1b			S				Novartis
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Q12h (2 U / 12 H)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	12905295	EXPEDITED (15-DAY)		OT	CA-ROCHE-1624144		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported

Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Vioxx	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Wellbutrin	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	12930360	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092641		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Remicade	S	Unknown			Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	13350239	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008095		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission; Product Dose Omission	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	2 Df, Unk		Apotex
	Apo-Prednisone			S	Unknown	2 Df, 1 Every 2 Days		Apotex
	Apo-Prednisone			S	Unknown	2 Df, Unk		Apotex
	Folic Acid			S	Unknown	Unk, Q.Wk.		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Actemra			S	Subcutaneous	162 Mg, Q.Wk.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	162 Mg, Q.Wk.		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported

Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Methotrexate	C	Unknown	25 Mg, Q.Wk.		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	13516413	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038202		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	13960284	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported

	Actemra	S	Unknown	Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	14217959	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Mirtazapine			S	Unknown	15 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	14241987	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021746		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased;	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

Therapeutic Product Effect Decreased	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Varenicline Tartrate	S	Oral	1 Df, Qd	Not Reported
	Varenicline Tartrate	S	Oral	Unk Unk, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Valtrex	C	Oral	1000 Mg, Bid	Not Reported
	Valtrex	C			Not Reported
	Rosuvastatin Calcium	C	Oral	Unk Unk, Qd (Once Every 24 Hours)	Not Reported
	Esomeprazole Magnesium W/Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	500 Mg, Bid	Not Reported
	Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Naproxen	C	Oral	500 Mg, Q.Wk.	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	14243129	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021953		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex

Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide		S	Unknown	20 Mg, Qd	Apotex
	Actemra		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	400 Mg, Qd	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Sulfasalazine		S	Oral	1 G, Qd	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	14453315	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2018CA006030		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Oxycodone Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported

Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Sulfasalazine	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported

	Xeljanz	S	Oral	1 Df, Q12h	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Prednisone	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	14471157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-004461		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	190 Milligram, Qwk		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Unknown	80 Milligram, Qd		Not Reported
	Methylprednisolone Acetate			C	Unknown	80 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	14689297	EXPEDITED (15-DAY)		OT	PHHY2018CA051657		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	14804432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110773		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Oral	Therapy Duration: 7 Years		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral	And 200 Mg Therapy Duration: 365.0	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Folic Acid	C	Oral		Not Reported
Tofacitinib Citrate	C	Oral		Not Reported
Abatacept	C			Not Reported
Leflunomide	C	Oral	Therapy Duration: 549.0 Nos	Not Reported
Leflunomide	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	15050148	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021593		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Bid		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown	25 Mg, 1 Every 2 Weeks		Not Reported

Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks For 4 Months And 6 Months	Not Reported
Humira	S	Unknown	40 Mg, Cyclical	Not Reported
Humira	S	Unknown	40 Mg, Q.O.Wk.	Not Reported
Methotrexate Sodium	S	Unknown	20 Mg, Q.Wk. (Therapy Duration: 790 Unit Unspecified)	Not Reported
Methotrexate Sodium	S	Unknown	200 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Unknown	15 Mg, Q.Wk.	Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Unk (Therapy Duration: 790 Unit Unspecified)	Not Reported
Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	200 Mg, Q.Wk.	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	1 G, Bid	Not Reported
Sulfasalazine	C			Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C			Not Reported
Bupropion	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	15258583	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167477		49 YR	Female	CAN

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

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Cosentyx		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	15662579	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570035-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	16215623	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-205616		35 YR	Female	ESP

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

Condition Aggravated; Exposure During Pregnancy; Live Birth	Hydroxychloroquine		S	Unknown	Unk		Sun
	Methylprednisolone Aceponate		S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	16387439	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-051014		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Glumetza			S	Unknown	500 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Topicorte			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

Altace	C	Unknown			Not Reported
Arava	C	Unknown			Not Reported
Asa	C	Unknown			Not Reported
Codeine	C	Unknown			Not Reported
D-Alpha Tocopherol	C	Unknown			Not Reported
Vitamin D [Ergocalciferol]	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Prednisone	C	Oral	Unk		Not Reported
Rosuvastatin Calcium	C	Unknown			Not Reported
Lyrica	C	Oral	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Tocopherol	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	16389901	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-017758		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Orencia			S	Intravenous (not otherwise specified)	200 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	300 Milligram, Qd		Not Reported

Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	16637381	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-071015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown	8 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	16799193	NON-EXPEDITED			US-PFIZER INC-2019393084		58 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	16907682	EXPEDITED (15-DAY)		CA, DS, OT	FR-AUROBINDO-AUR-APL-2019-065846		259 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Paracetamol			S	Transplacental	Unk		Aurobindo
	Keppra			S	Unknown	3000 Milligram, Daily		Not Reported
	Keppra			S	Transplacental	Unk		Not Reported
	Plaquenil			S	Transplacental	Unk		Not Reported
	Trileptal			S	Transplacental	Unk		Not Reported
	Actonel			C	Transplacental	Unk		Not Reported
	Cortancyl			C	Transplacental	Unk		Not Reported
	Diffu-K			C	Transplacental	Unk		Not Reported
	Kaleorid			C	Transplacental	Unk		Not Reported
	Orocal D3			C	Transplacental	Unk		Not Reported
	Speciafoldine			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	16999211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2451805		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17037780	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2461506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	5.0 Month(S)		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Triamcinolone			S				Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	2.0 Month(S)		Not Reported
	Humira			S	Unknown			Not Reported

Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	4.0 Month(S)	Not Reported
	Kineret	S	Subcutaneous	1.0 Year(S)	Not Reported
	Kineret	S			Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	2.0 Month(S)	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17404137	EXPEDITED (15-DAY)		CA, HO, OT	NVSC2020CA032705		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

Diabetes Mellitus; Wound Infection			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported
	Erythromycin	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17533813	EXPEDITED (15-DAY)		OT	NVSC2020CA069732		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methadone			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Df, Unknown		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Enbrel	S	Unknown	50 Mg	Not Reported
Enbrel	S	Unknown	Unk (Solution For Injection In Pre-Filled Syringe)	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	50 Mg	Not Reported
Zingiber Officinale	C	Oral	500 Mg	Not Reported
Zingiber Officinale	C	Unknown	500 Mg	Not Reported
Xalatan	C	Ophthalmic	50 Mg, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Valsartan	C	Unknown	320 Mg, Qd	Not Reported
Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Jamp K20	C	Unknown	1500 Mg, Qd	Not Reported
Gravol	C	Oral	500 Mg	Not Reported
Furosemide	C	Unknown	40 Mg, Qd	Not Reported
Estrogel	C	Unknown	1 Df, Qd	Not Reported
Estrogel	C	Unknown	Unk Unk, Tid	Not Reported
Estradiol	C	Unknown	0.6 % Tid	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qd	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk Unk, Bid (2 Every 1 Days)	Not Reported
Calcium	C	Unknown	500 Mg, Qd	Not Reported

Acetaminophen	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17665283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021759		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Hydroxychloroquine			S	Oral	2 Df, Qd		Apotex
	Hydroxychloroquine			S	Oral	5 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Cyclosporin			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported

Methotrexate Sodium	S	Oral	20 Mg, Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituximab	S	Endocervical	Unk	Not Reported
Rituximab	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	2 Df, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	Unk, Qd	Not Reported
Xeljanz	C	Oral	Unk	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz Xr	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17682830	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031430		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17709446	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004003877			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Abnormal; Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	600 Mg, Qd, Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Tocilizumab			C		200 Mg		Not Reported
	Cholecalciferol			C		Unk 3300iu/Mi		Not Reported
	Nitazoxanid			C		500 Mg		Not Reported
	Azithromycin			C		500 Mg		Not Reported
	Bisacodyl			C		5 Mg		Not Reported
	Ceftriaxone			C		1 G		Not Reported
	Enoxaparin Sodium			C		40mg/0.4ml		Not Reported
	Metamizole Sodium			C		1 G		Not Reported
	Midazolam			C		5 Mg		Not Reported
	Etomidate			C		20 Mg		Not Reported

Esomeprazol	C	40 Mg		Not Reported
Ondantor	C	8 Mg		Not Reported
Furosemide	C	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17742768	EXPEDITED (15-DAY)		HO	CA-ROCHE-2592005		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17749213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592694		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Supeudol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17754239	EXPEDITED (15-DAY)		DS, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246200		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligrams, Daily		Sun
	Nivaquine 100 Mg, Comprime Secable			S	Oral	2-3 Cp Par Jour		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	2-3 Cp Par Jour		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17779338	EXPEDITED (15-DAY)		DE	CA-ROCHE-2597863			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported

	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17814493	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597972			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported

Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17814506	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597907			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17820577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600353		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17826310	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005511			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Multiple Organ	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Bid		Concordia

Dysfunction Syndrome; Off Label Use; Ventricular Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	200 Mg, Bid	Concordia
	Azithromycin		S	Unknown	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17829730	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2606587		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Pyrexia; Red	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported

	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intramuscular	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17861134	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606920			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Erythematosus; Treatment Failure; Wound	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17866903	EXPEDITED (15-DAY)		DE	LU-ELI_LILLY_AND_COMPANY-LU202006001577		83 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Tachycardia	Zyprexa			S	Oral	5 Mg, Daily		Eli Lilly And Co
	Tiapridal			S	Oral	50 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Bid		Not Reported

	Aprovel	C	Oral	150 Mg, 12 Hours	Not Reported
	Tazobactam	C	Intravenous (not otherwise specified)	4 G, Every 8 Hrs	Not Reported
	Doxycycline	C	Oral	100 Mg, Bid	Not Reported
	Trajenta	C	Oral	5 Mg, Daily	Not Reported
	Levemir	C	Subcutaneous	12 International Unit, Daily	Not Reported
	Dafalgan	C	Oral	1 G, Every 6 Hrs In Case Of Fever	Not Reported
	Metoprolol Eg [Metoprolol Succinate]	C	Oral	100 Mg, Every 12 Hours	Not Reported
	Mirapexin	C	Oral	0.18 Mg, Every 12 Hours	Not Reported
	Clexane	C	Subcutaneous	40 Mg, Daily	Not Reported
	Piperacillin	C	Intravenous (not otherwise specified)	4 G, Every 8 Hrs	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17884034	EXPEDITED (15-DAY)		DE, OT	FR-ROCHE-2616494		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hepatocellular Injury	Roactemra			S	Unknown			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17885854	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017329916		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Intentional Product Use Issue	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, 1x/Day (Od)		Pfizer

	Xeljanz	S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil	S	Oral	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17899356	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3445633-00		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Long Qt Syndrome	Kaletra			S	Oral			Not Reported
	Azitromicina			S	Unknown			Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Metilprednisolona			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17902651	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-045262		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, 1 Every 1 Week		Not Reported
	Asa			C	Unknown	81 Milligram		Not Reported
	Ergocalciferol			C	Unknown			Not Reported

Lantus	C	Subcutaneous	Unk		Not Reported
Lozide [Indapamide]	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown			Not Reported
Ramipril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17909926	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619848		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Hydrocortisone	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Not Reported
Topicort [Desoximetasone]	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

	Atasol With Codeine-Caffeine		C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17914344	EXPEDITED (15-DAY)		DE, HO, OT	ES-PFIZER INC-2020232499		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrial Fibrillation; Cardiac Failure; Death; Pyrexia; Renal Failure; Respiratory Failure	Azithromycin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Methylprednisolone Acetate			S		Lower Doses (+/- 1mg/Kg Per Day)		Not Reported
	Methylprednisolone Acetate			S		Unk		Not Reported
	Methylprednisolone Acetate			S		Unk		Not Reported
	Lopinavir + Ritonavir			S		Unk		Not Reported
	Lopinavir + Ritonavir			S		Unk		Not Reported
	Lopinavir + Ritonavir			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Ertapenem Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17914440	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES-1788339		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rezolsta 800 Mg / 150 Mg			S	Oral	1 Dosage Forms		Not Reported

	Comprimidos Recubiertos Con Pelicula 30 Compr Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid	C	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17914494	EXPEDITED (15-DAY)		DE, HO	FR-CELLTRION INC.-2020FR023386			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Covid-19 Pneumonia; Death; Intentional Product Use Issue; Off Label Use	Rituximab (Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17914509	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17914625	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050515			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Qd		Zydus Pharm
	Theralene			S	Oral	50 Milligram, Qd		Not Reported
	Loxapine			S	Oral	155 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Milligram, Qd		Not Reported
	Paracetamol			C	Oral	1 Gram		Not Reported
	Nicopatch			C	Transdermal	7 Milligram		Not Reported
	Diazepam			C	Oral	10 Milligram		Not Reported
	Atorvastatine [Atorvastatin Calcium]			C	Oral	40 Milligram		Not Reported
	Nicotine			C	Oral	12 Milligram		Not Reported
	Macrogol 4000			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	7.5 Milligram		Not Reported
	Zopiclone			C	Oral	7.5 Milligram		Not Reported
	Ramipril			C	Oral	1.25 Milligram		Not Reported
	Akineton [Biperiden Hydrochloride]			C	Oral	4 Milligram		Not Reported
	Ezetimibe			C	Oral	10 Milligram		Not Reported
	Kardegic			C	Oral	75 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17914806	EXPEDITED (15-DAY)		OT	CA-ROCHE-2626116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17914976	NON-EXPEDITED			NVSC2020US171371		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Signifor Lar			S	Unknown	60 Mg Every 4 Weeks		Novartis
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915139	EXPEDITED (15-DAY)		DE	US-SPECGX-T202001119			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Oxycodone			S	Unknown	5 Milligram		Mallinckrodt
	Oxycodone			S	Unknown	15 Milligram		Mallinckrodt
	Oxycodone/Acetaminophen			S	Unknown	Unk		Mallinckrodt

Oxycodone/Acetaminophen	S	Unknown	Unk	Mallinckrodt
Citalopram	S	Unknown	20 Milligram, Qd	Not Reported
Promethazine	S	Unknown	25 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Gabapentin	S	Unknown	300 Milligram	Not Reported
Diphenhydramine	S	Unknown	Unk	Not Reported
Caffeine	S	Unknown	Unk	Not Reported
Azithromycin	C	Unknown	250 Milligram	Not Reported
Lexapro	C	Unknown	10 Milligram	Not Reported
Klor-Con	C	Unknown	10 Milliequivalent	Not Reported
Protonix	C	Unknown	40 Milligram	Not Reported
Lorazepam	C	Unknown	1 Milligram	Not Reported
Metronidazole	C	Unknown	0.75 Percent	Not Reported
Prednisone	C	Unknown	10 Milligram	Not Reported
Pentazocine And Naloxone	C	Unknown	Unk (50-0.5)	Not Reported
Indomethacin	C	Unknown	25 Milligram	Not Reported
Levaquin	C	Unknown	500 Milligram	Not Reported
Triamcinolon	C	Unknown	0.1 Percent	Not Reported
Enalapril Maleate	C	Unknown	5 Milligram	Not Reported
Furosemide	C	Unknown	20 Milligram	Not Reported
Clindamycin	C	Unknown	150 Milligram	Not Reported
Indapamide	C	Unknown	2.5 Milligram	Not Reported
Actonel	C	Unknown	35 Milligram	Not Reported
Lidocaine	C	Unknown	3 Percent	Not Reported
Enalapril	C	Unknown	5 Milligram	Not Reported
Enalapril	C	Unknown	20 Milligram	Not Reported
Azathioprine	C	Unknown	50 Milligram	Not Reported
Endocet	C	Unknown	Unk (10-325 Mg)	Not Reported
Metformin	C	Unknown	500 Milligram	Not Reported

Glyburide	C	Unknown	5 Milligram		Not Reported
Metolazone	C	Unknown	5 Milligram		Not Reported
Potassium Chloride	C	Unknown	10 Milliequivalent		Not Reported
Pantoprazole	C	Unknown	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915144	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915166	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046902		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Cardiac Disorder; Diverticulitis; Drug Ineffective; Joint Injury; Joint Swelling;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Terminal State; Thrombosis	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown		Not Reported
	Ilaris		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915275	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-215199		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; False Positive Investigation Result	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915282	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047170		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Intravenous (not otherwise specified)	25 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915391	NON-EXPEDITED			US-APPCO PHARMA LLC-2086112			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suspected Product Quality Issue	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915418	NON-EXPEDITED			US-APPCO PHARMA LLC-2086115		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Drug Ineffective; Pain; Swelling	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915460	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1788670		68 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatic Function Abnormal; Hyperbilirubinaemia	Hydroxychloroquine			S	Oral	400 Mg		Teva
	Clarithromycin			C				Not Reported
	Metoclopramide			C				Not Reported
	Norepinephrine			C				Not Reported
	Amoxicilina + Ácido Clavulânico			C				Not Reported
	Rocuronium Bromide			C				Not Reported
	Paracetamol			C				Not Reported
	Hydrocortisone			C				Not Reported
	Midazolam			C				Not Reported
	Morphine			C				Not Reported

	Lopinavir + Ritonavir	C		Not Reported
	Enoxaparin Sodium	C		Not Reported
	Propofol	C		Not Reported
	Esomeprazole	C		Not Reported
	Epinephrine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915491	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1788205		68 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Liver Disorder	Hydroxychloroquine			S	Oral	200mg From 12 / 12h. 400 Mg		Teva
	Letrozole			C	Oral			Not Reported
	Paracetamol			C				Not Reported
	Metoclopramide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Fosinopril			C	Oral			Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915500	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1788204		74 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatic Function Abnormal	Hydroxychloroquine			S	Oral	200mg De 12/12h. 400 Mg		Teva
	Morphine			C				Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)			Not Reported
	Clarithromycin			C				Not Reported
	Lopinavir + Ritonavir			C	Oral			Not Reported
	Rocuronium Bromide			C	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin Sodium			C				Teva
	Propofol			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915519	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1789421		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915520	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1789107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tofacitinib	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Rabeprazole Sodium	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915527	EXPEDITED (15-DAY)		OT	CA-ROCHE-2625282		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration 366.0		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915556	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3449368-00		68 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatic Function Abnormal; Hyperbilirubinaemia	Kaletra			S	Oral			Not Reported
	Plaquinol			S	Oral	200mg De 12/12h, Redução Para 100 Mg 12/12h E Depois Suspensão		Not Reported
	Metoclopramide			C				Not Reported
	Morphine			C				Not Reported
	Propofol			C				Not Reported
	Epinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Rocuronium Bromide			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Dutasteride			C				Not Reported
	Clarithromycin			C				Not Reported
	Paracetamol			C				Not Reported
	Esomeprazole			C				Not Reported
	Amoxicilina + Acido Clavulanico			C				Not Reported
	Hydrocortisone			C				Not Reported
	Silodosin			C				Not Reported
	Losartan + Hidroclorotiazida			C				Not Reported
	Bisoprolol			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915661	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1789390		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915876	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1789066		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17915996	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047216		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Oral	20 Milligram		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram		Not Reported
Neoral	S	Oral			Not Reported
Neoral	S	Subcutaneous			Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Sulfasalazine	S	Oral			Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz Xr	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916050	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624661		55 YR	Female	CAN

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

					otherwise specified)					
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916134	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047197		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	Unk, Qd		Not Reported
	Docosahexanoic Acid;Eicosapentaenoic Acid			C	Unknown	1200 Milligram, Bid		Not Reported
	Ergocalciferol			C	Intravenous (not otherwise specified)	400 International Unit, Qwk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	40 Milligram, Bid		Not Reported
	Ferrous Gluconate			C	Unknown	300 Milligram, Qd		Not Reported
	Loperamide Hydrochloride			C	Unknown	2.5 Milligram		Not Reported

	Nasonex	C	Unknown	Unk, Bid	Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown	40 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	5 Milligram	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
	Tylenol	C	Oral	1000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916234	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202006006359			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916264	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1057704		79 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Diarrhoea; Off Label Use; Transaminases Increased	Lopinavir/Ritonavir Mylan			S	Oral	2cp 12/12h		Mylan
	Plaquinol			S	Oral	400mg 12/12h D1, 200mg 12/12h Dias Seguintes		Mylan
	Hydroxyzine			C		Unk		Mylan
	Bromazepam			C		Unk		Mylan
	Colchicine			C		Unk		Mylan
	Indapamide			C		Unk		Mylan
	Enoxaparin Sodium			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916277	EXPEDITED (15-DAY)		OT	CA-ACCORD-185835			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916436	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015828		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported

Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916495	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619138		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Certolizumab Pegol	S	Unknown		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916544	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-029			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Malaise; Night Sweats; Nightmare; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome	Methotrexate			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916757	EXPEDITED (15-DAY)		OT	CA-ACCORD-185908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916784	EXPEDITED (15-DAY)		HO	CA-ACCORD-185739		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate	Alendronate Sodium/Alendronic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Codeine	S			Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Actemra	S	Unknown	1 Every 1 Months	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Leflunomide	S	Oral		Not Reported
	Myochrysine	S	Parenteral	1 Every 1 Months, Solution Intramuscular	Not Reported
	Orencia	S	Unknown	1 Every 1 Weeks	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Every 12 Hours	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported
	Actemra	S	Unknown	1 Every 4 Weeks	Not Reported
	Enbrel	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 2 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 1 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 1 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 1 Weeks	Accord
	Methotrexate	S	Oral	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord

	Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Accord
	Methotrexate	S	Subcutaneous	1 Every 2 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17917183	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020232752		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Lopinavir + Ritonavir			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Daily		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	800 Mg, Daily		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17917325	DIRECT	Y	OT				Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17917613	EXPEDITED (15-DAY)		HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001893			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Torsade De Pointes	Hydroxychloroquine			S	Oral	800 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Ipca
	Fluconazole			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17917930	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046450		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every One Day		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	200 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Anakinra			C	Unknown	100 Milligram		Not Reported
	Ativan			C	Unknown	Unk		Not Reported

Codeine	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown		Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Furosemide	C	Unknown	40 Milligram, Tid	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram	Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Vagifem	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919203	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3448896-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Liver Function Test Increased; Musculoskeletal Pain;	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919437	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2673128-00		57 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919709	EXPEDITED (15-DAY)		HO	NVSC2020ES171444		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycina			S	Oral	500 Mg, Qd		Novartis
	Azithromycina			S				Novartis
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxona			S				Not Reported
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919738	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-20105			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Tocilizumab			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Apo-Prednisone			S	Unknown	Unknown		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unknown		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral	Unknown		Not Reported
	Diclofenac Sodium			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Intra-arterial	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Subcutaneous	Unknown		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Oral	Unknown		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919750	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-20079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Etanercept			S	Unknown	Unknown		Not Reported
	Amlodipine Besilate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	16438417	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033193			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Topical	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hcl			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Subcutaneous	1 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Topicort	S	Unknown	Unk	Not Reported
	Topicort	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	16801774	EXPEDITED (15-DAY)		OT	PHHY2019CA210752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

	Cimzia		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Otezla		S	Oral	Unk	Not Reported
	Otezla		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	16805717	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2921109-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

	Methotrexate		C	Unknown	Not Reported
	Arava		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	16854139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2409782		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S),1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Mefenamic Acid			C	Unknown			Not Reported

	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17306364	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-003471		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported
	Calcium			S	Unknown	Unk		Not Reported
	Fosinopril			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Vitamin D			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17667117	EXPEDITED (15-DAY)		OT	NVSC2020CA098733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Morphine Sulphate	S	Unknown	Unk	Not Reported
	Arava	S	Oral	10 Mg, Qd	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Dilaudid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17769446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596822			Female	CAN

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

Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituxan	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17804959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599174		63 YR	Female	CAN

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

	Leflunomide	S			Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single Use Prefilled Syringe	Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17810508	EXPEDITED (15-DAY)		OT	CA-ROCHE-1962205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Gold Sodium Thiomalate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17835335	EXPEDITED (15-DAY)		HO, LT, OT	IT-ACCORD-183181		27 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Mycophenolic Acid			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone/Prednisone Acetate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17919630	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-029391		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination	Azithromycin			S	Oral	Unk		Aurobindo
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Interferon Beta-1b			S	Unknown	250 Milligram, 48 Hours		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Kaletra			C	Unknown	Unk		Not Reported
	Genvoya			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920024	EXPEDITED (15-DAY)		HO	NVSC2020ES170971		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Thrombocytopenia	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S				Novartis

	Enoxaparina		S	Subcutaneous	40 Mg, Qd	Not Reported
	Ceftriaxona		S	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
	Ceftriaxona		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920087	EXPEDITED (15-DAY)		OT	CA-ACCORD-185834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Reactine (Cetirizine)			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920088	EXPEDITED (15-DAY)		OT	CA-ACCORD-185832			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort			S	Topical			Not Reported
	Orencia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920089	EXPEDITED (15-DAY)		OT	CA-ACCORD-185892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia;	Methotrexate			S				Not Reported
	Actemra			S				Not Reported

Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous, Single-Use Prefilled Syringe	Not Reported
	Cortisone	S	Unknown		Not Reported
	Diclofenac	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920090	EXPEDITED (15-DAY)		OT	CA-ACCORD-185907			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

	Arava	S		Not Reported
	Cetirizine	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S		Not Reported
	Fosamax	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S		Not Reported
	Prednisone	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920091	EXPEDITED (15-DAY)		OT	CA-ACCORD-185898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Prefilled Syringe		Not Reported
	Cortisone			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920112	EXPEDITED (15-DAY)		OT	CA-ACCORD-185838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920116	EXPEDITED (15-DAY)		OT	CA-ACCORD-185909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown	1 Every 1 Days		Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported

	Tofacitinib	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Abatacept	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920273	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1789459		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Erythema; Drug Ineffective; Hypoacusis; Off Label Use; Product Use Issue; Psoriatic Arthropathy	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920295	EXPEDITED (15-DAY)		OT	CA-ACCORD-185844			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia (Abatacept)			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920296	EXPEDITED (15-DAY)		OT	CA-ACCORD-185836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920298	EXPEDITED (15-DAY)		OT	CA-ACCORD-185848			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920344	EXPEDITED (15-DAY)		OT	NVSC2020ES171974		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Mg, Qd		Novartis
	Amoxicillin, Clavulanic Acid			S	Oral	Unk Unk, Q8h		Not Reported
	Metronidazole			S	Oral	Unk		Not Reported
	Dolquine			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920402	EXPEDITED (15-DAY)		DE	NVSC2020FR172931			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Azithromycin			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920404	EXPEDITED (15-DAY)		DE, OT	NVSC2020FR172751			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Azithromycin			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920408	EXPEDITED (15-DAY)		LT	NVSC2020FR172172		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	Unk		Novartis
	Plaquenil			S	Oral	Unk		Not Reported
	Tazobactam			C	Intravenous drip	Unk		Not Reported
	Piperacilline			C	Intravenous drip	Unk		Not Reported
	Paracetamol			C	Intravenous bolus	Unk		Not Reported
	Linezolide			C	Intravenous bolus	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17920416	EXPEDITED (15-DAY)		OT	NVSC2020ES171050		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Novartis
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported

	Ceftriaxona	S				Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Tocilizumab	C				Not Reported
	Azithromycin	C	Oral	500 Mg, Qd		Not Reported
	Azithromycin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	15995703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2674768-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Vaginal	Dosage Form Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown	Spray, Metered Dose		Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Synthroid			C	Unknown			Not Reported

	Vagifem	C	Unknown		Not Reported
	Pantoloc	C		(Enteric Coated)	Not Reported
	Darifenacin Hydrobromide	C			Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	Plantago Ovata	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	16738036	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2019SK195615		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Pneumonia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Ciclosporin			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17920789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606480		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Folic Acid	C		Not Reported
	Naproxen	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	12722977	EXPEDITED (15-DAY)		DS	CA-ROCHE-1826508			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 8.0		Not Reported

Rheumatoid Arthritis				Year(S)	
	Methotrexate	S	Oral	3285.0 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Hydromorphone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	12770694	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076721		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Joint Injury; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C	Unknown	2 Milligram, Qd	Not Reported
	Hydromorphone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	13091577	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875078		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Incorrect Route Of Product Administration; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Sodium Aurothiomalate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	13718178	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP013781		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	13968222	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not	750 Mg, Unk		Not Reported

				otherwise specified)		
	Remicade		S			Not Reported
	Enbrel		S	Unknown	8 Mg, Unk	Not Reported
	Orencia		S	Intracardiac	750 Mg, Unk	Not Reported
	Meloxicam		C	Unknown	Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	14238496	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021706			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Varenicline Tartrate			S				Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Valtrex	C	Unknown	Unk		Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	14778690	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009926			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, 3 Every 1 Weeks		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Weeks		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Q.O.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, B.I.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	15330290	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Discomfort; Uveitis	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	40 Mg, Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Unk	Not Reported
	Cimzia	C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	15356144	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2179236		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ilaris	S	Unknown		Not Reported
	Ilaris	S			Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Unknown	Solution For Injection	Not Reported
	Humira	S			Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	15801139	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617050-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Aleve	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Folic Acid	C	Subcutaneous	Not Reported
	Methotrexate	C		Not Reported
	Plaquenil	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	15925154	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-005710		40 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Toxicity; Cytomegalovirus Infection; Cytomegalovirus Mucocutaneous Ulcer; Febrile Neutropenia; Leukoplakia;	Amlodipine			S	Unknown	Unk		Aurobindo
	Sildenafil			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	100 Milligram, Once A Day		Not Reported
	Azathioprine			S				Not Reported

Odynophagia; Oropharyngeal Candidiasis; Pancytopenia; Product Use Issue; Red Blood Cell Poikilocytes Present; Vitamin D Deficiency	Hydroxychloroquine		S	Unknown	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine		S			Not Reported
	Prednisolone		S	Unknown	1 Milligram/Kilogram, Once A Day	Not Reported
	Prednisolone		S	Unknown	60 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	15930738	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655654-00		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Altace	C	Unknown		Not Reported
	Asa	C			Not Reported
	D-Alpha Tocopherol	C			Not Reported
	Folic Acid	C	Unknown	1.0	Not Reported
	Methotrexate	C	Oral		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Vitamin D	C	Unknown		Not Reported
	Docosahexaenoic Acid	C			Not Reported
	Eicosapentaenoic Acid	C			Not Reported
	Acetaminophen	C			Not Reported
	Arava	C			Not Reported
	Codeine	C			Not Reported
	Ergocalciferol	C			Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	16174045	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2736313-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Actavis			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	16242893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Enzyme Increased; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enalapril Maleate			S	Unknown			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Cephalexin Monohydrate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Lopressor			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Penicillin G (2-Amino-4-Methoxy-6-Methylpyrim)			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported

Celebrex	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Biaxin Xl	S	Unknown	Not Reported
Cephalexin	S	Unknown	Not Reported
Clindamycin Hydrochloride	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Tecta	S	Unknown	Not Reported
Keflex	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Hctz	S	Unknown	Not Reported
Hydralazine Hydrochloride	S	Unknown	Not Reported
Levaquin	S	Unknown	Not Reported
Metoprolol Tartrate	S	Unknown	Not Reported
Moxifloxacin Hydrochloride	S	Unknown	Not Reported
Pariet	S	Unknown	Not Reported
Gliclazide	S	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Colchicine	C	Unknown	Not Reported
Coversyl	C	Unknown	Not Reported
Leucovorin	C	Unknown	Not Reported
Levothyroxine Sodium	C	Unknown	Not Reported
Ranitidine	C	Unknown	Not Reported
Atenolol	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Iron Sucrose	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported

	Veltassa	C	Unknown	Not Reported
	Venofer	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	16387698	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-APL-2019-029940		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis;	Alendronic Acid Tablets			S	Unknown	70 Milligram, Every Week		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, 4 Every Week		Aurobindo
	Actemra			S	Unknown	2.68 Milligram,Once Every 4 Weeks		Not Reported
	Actemra			S	Unknown	360 Milligram,Once In A Month		Not Reported
	Actemra			S	Unknown	360 Milligram, Every Week		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	360 Milligram,Once Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	680 Milligram, Every Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	360 Milligram, Every Month		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Every Week		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	60 Milligram, Two Times A Day		Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported

Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week (50 Milligram)	Not Reported
	Enbrel	S	Unknown	25 Milligram, 1 Every 2 Week	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Once A Day	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.0 Milligram,Once In Aweek	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	70.0 Milligram,Once In Aweek	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Oral	10.0 Milligram,Once In A Week	Not Reported

Methotrexate	S	Subcutaneous	12.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,4 Every 1 Year	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
Mogadon	S	Oral	5 Milligram	Not Reported
Myochrysine	S	Parenteral	50 Milligram,Once In A Month (Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Every Week	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Every Two Weeks	Not Reported

Nitrazepam	S	Oral	5 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram,Once In A Week	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	760 Milligram, Every Week	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Every Week	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	16388023	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-030040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Milligram, Once A Day		Not Reported
	Ciclosporin			C	Unknown	150 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17040026	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3002083-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound			otherwise specified)	Intravenous	
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Arava	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Reactine[Cetirizine Hydrochloride]	S	Unknown		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Topical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Diclofenac	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Arava	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Atasol [Paracetamol]	C			Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17227609	EXPEDITED (15-DAY)		HO	CA-ROCHE-2415329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Parenteral	Solution Intramuscular		Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17242744	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026838		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use;	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine	S	Unknown	Unk		Apotex
	Actemra	S	Subcutaneous	162 Mg, Unk		Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate	S	Oral	10 Mg, Unk		Not Reported
	Orencia	S	Subcutaneous	125 Mg, Q.Wk.		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17443585	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552671		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17667774	EXPEDITED (15-DAY)		OT	NVSC2020CA098830			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Burning Sensation; C-Reactive Protein Increased; Colitis; Diarrhoea; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Cosentyx			S	Unknown	150 Mg, Unknown		Novartis
	Methotrexate			S	Oral	15 Mg, Unknown		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk Unk, Unknown		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported
	Orencia			S				Not Reported
	Otezla			S	Oral	30 Mg, Bid		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17673259	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009906		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Adalimumab			S	Unknown	40 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

Rheumatoid Arthritis			otherwise specified)		
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, Tid	Not Reported
	Tylenol Arthritis	C	Unknown	650 Mg, Qid	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17705027	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003546			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Coronavirus Infection; Hepatocellular Injury; Off Label Use; Pulmonary Embolism	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd		Concordia
	Paracetamol			C		Unk		Not Reported
	Rocephine			C		Unk		Not Reported
	Spiramycine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Cefazolin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17753394	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-021569		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk,Not Specified		Aurobindo
	Ceftriaxone			S	Unknown	Unk,Not Specified		Not Reported
	Midazolam			S	Unknown	Unk		Not Reported
	Midazolam			S				Not Reported
	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported
	Dolquine			S	Oral	200 Milligram, Two Times A Day (A Compressed Breakfast And Dinne)		Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Manidon Hta			C	Unknown	Unk		Not Reported
	Rilast			C	Unknown	Unk		Not Reported
	Omnic Ocas			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Kalpress			C	Unknown	Unk		Not Reported
	Cortic			C	Unknown	Unk,Low Dose Corticoids		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17779152	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832233		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Apo-Hydroxyquine	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	C	Unknown	Not Reported
Sodium Aurothiomalate	C		Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17807339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598571		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Methyl Salicylate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Salicylates Nos	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17830092	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599257		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction;	Actemra			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Ophthalmic			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Paracetamol	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17857770	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005006066			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatocellular Injury; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Coated Tablet		Concordia
	Sarilumab			S	Intravenous (not otherwise specified)	400 Mg, Qd Once		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Amlodipine			C		Unk		Not Reported
	Indapamide			C		Unk		Not Reported
	Kcl			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Cefotaxime			C		Unk		Not Reported
	Spiramycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17881803	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200607083		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Anakinra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17890395	EXPEDITED (15-DAY)		DE	NVSC2020ES162466		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Novartis
	Tacrolimus			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Df, Q12h		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Mg, Qd		Not Reported
	Prednisona			C	Oral	20 Mg, Qd		Not Reported
	Ceftriaxona			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17914648	EXPEDITED (15-DAY)		HO	NVSC2020ES169554		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina			S	Oral	500 Mg, Qd (500 Mg Dia)		Novartis
	Dolquine			S	Other	400 Mg, Qd		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17920839	EXPEDITED (15-DAY)		HO	ES-CELLTRION INC.-2020ES023380			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	5 G, Total		Not Reported
	Micofenolato De Mofetilo Stada			S	Oral	500 Mg, Every 12 Hours		Not Reported

	Micofenolato De Mofetilo Stada	S	Oral	1 G, Every 12 Hours	Not Reported
	Dolquine	S	Oral	200 Mg, Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17920906	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Sulfate]				
Pseudoephedrine Hydrochloride		S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
Remicade		S	Intravenous (not otherwise specified)	Not Reported
Sarilumab		S	Unknown	Not Reported
Simponi		S	Subcutaneous	Not Reported
Stelara		S	Unknown	Not Reported
Sulfasalazine		S	Oral	Not Reported
Topicort [Desoximetasone]		S	Subcutaneous	Not Reported
Xeljanz		S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17920969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2622344			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17920973	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202006006405			Unknown	CAN

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

Pulmonary Fibrosis; Retinopathy	Hydroxychloroquine	S	Oral	400 Mg, Qd		Concordia
	Arava	S	Oral	10 Mg, Qd		Not Reported
	Methotrexate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921047	EXPEDITED (15-DAY)		OT	CA-ROCHE-2626112		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Retinal Toxicity	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921149	EXPEDITED (15-DAY)		OT	AU-ORION CORPORATION ORION PHARMA-20_00009470		44 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus; Drug Ineffective For Unapproved Indication; Product Use In Unapproved Indication	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Diprosone			S	Topical			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Novosone			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921199	EXPEDITED (15-DAY)		HO	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-052104			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Colitis	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921252	EXPEDITED (15-DAY)		DS, OT	JP-ADVANZ PHARMA-GSH201803-000984			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Condition Aggravated; Osteoarthritis; Thrombocytopenia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Methylprednisolone			S	Intravenous (not otherwise specified)	50 Mg, Qd		Not Reported
	Artz			S	Intra-articular	50 Mg, Single		Not Reported
	Artz			S				Not Reported
	Baktar			C		Unk		Not Reported
	Baktar			C				Not Reported
	Rabeprazole Na			C		Unk		Not Reported
	Rabeprazole Na			C				Not Reported
	Trazenta			C		Unk		Not Reported
	Bonoteo			C		Unk		Not Reported
	Bonoteo			C				Not Reported
	Humalog			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921589	EXPEDITED (15-DAY)		HO	US-LAURUS LABS LIMITED-202000118		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged;	Hydroxychloroquine			S	Oral			Unknown

Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Nausea; Somnolence; Suicide Attempt; Toxicity To Various Agents; Ventricular Tachycardia; Vomiting	Methotrexate		S	Oral	Not Reported
	Prednisone		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619211		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 1095.0 Days		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous	Therapy Duration:1095.0 Days		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 91.0 Days		Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 91.0 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 91.0 Days		Not Reported
	Prednisone			S	Unknown	Therapy Duration: 91.0 Days		Not Reported
	Remicade			S	Intravenous (not	Therapy Duration: 366.0		Not Reported

				otherwise specified) Days	
	Xeljanz		S	Oral	Not Reported
	Cetirizine Hydrochloride		C		Not Reported
	Cortisone		C		Not Reported
	Dexamethasone		C		Not Reported
	Gabapentin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1790818			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1790821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Orencia	S	Unknown		Not Reported
Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921849	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1790823			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921937	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1790816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921950	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	200 Milligram, 1 Every 1days		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, 1 Every 1 Days		Not Reported
	Methotrexate			S	Oral	20 Milligram, 1 Every 1 Days		Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17921953	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049280		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumerate	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17922051	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2619593		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported

Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Powder For Solution Subcutaneous	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17922097	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049228		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	200 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17922132	EXPEDITED (15-DAY)		HO	NVSC2020ES173041		50 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone			S				Not Reported

	Dolquine		S	Oral	400 Mg, Qd	Not Reported
	Dolquine		S			Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17922156	EXPEDITED (15-DAY)		OT	CA-ACCORD-185905			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Metaraminol			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17922167	EXPEDITED (15-DAY)		OT	US-ACCORD-185701			Unknown	USA

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

Brugada Syndrome; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine		S	Twice Daily, For 2 Doses, Then 6.5 Mg/Kg, Once Daily, For 4 Doses	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923013	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049358		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported
	Tenormin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Elavil [Allopurinol]			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923032	EXPEDITED (15-DAY)		HO, LT, OT	IT-TEVA-2020-IT-1790127		34 YR	Female	ITA

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

Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome; Drug Ineffective	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Teva
	Methylprednisolone	S	Unknown	80 Milligram Daily;		Not Reported
	Methylprednisolone	S				Not Reported
	Norepinephrine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923126	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200617820		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923151	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1789179		48 YR	Male	ESP

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

Hepatitis	Amoxicilina + Ácido Clavulánico	S	Unknown		Teva
	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;	Teva
	Meropenem (7155a)	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923192	EXPEDITED (15-DAY)		LT	GB-ACCORD-186224		59 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypotension; Palpitations; Tachycardia	Hydroxychloroquine			S	Oral			Not Reported
	Verapamil			C				Not Reported
	Doxazosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923216	EXPEDITED (15-DAY)		OT	CA-ACCORD-185902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923225	EXPEDITED (15-DAY)		OT	CA-ACCORD-185875			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine			S	Unknown			Accord
	Methotrexate			S	Unknown			Accord
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	Frequency: 1 Every 1 Days		Not Reported
	Leflunomide			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923294	EXPEDITED (15-DAY)		OT	CA-ACCORD-185853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported

	Plaquenil	S			Not Reported
	Prednisone	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923297	EXPEDITED (15-DAY)		OT	CA-ACCORD-185866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Metaraminol			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous,Single-Use Prefilled Syringe		Not Reported
	Cortisone			S				Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Alendronic Acid			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Pseudoephedrine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

				otherwise specified)				
	Golimumab		S	Subcutaneous	Solution For Injection In Pre-Filled Pen			Not Reported
	Reactine [Cetirizine]		S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924024	EXPEDITED (15-DAY)		OT	ES-ACCORD-186289		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Oral			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Oral			Not Reported
	Kaletra			S	Oral	Strength: 200/50 Mg, 120 Tablets		Not Reported
	Micafungin/Micafungin Sodium			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924099	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020238690		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	Unk		Pfizer
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Interferon Beta-1b			S		250 Mg, Alternate Day (Every 48 Hours)		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Kaletra			C		Unk		Not Reported
	Genvoya			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924137	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1788957		68 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Impaired Gastric Emptying	Hydroxychloroquine			S	Oral	200 Mg 12 / 12h, Unit Dose: 400 Mg		Teva
	Esomeprazole			C				Not Reported
	Morphine			C				Not Reported
	Rocuronium Bromide			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Amoxicilina + Acido Clavulanico			C				Not Reported
	Epinephrine			C				Not Reported
	Norepinephrine			C				Not Reported
	Paracetamol			C				Not Reported
	Clarithromycin			C				Not Reported
	Metoclopramide			C				Not Reported
	Hydrocortisone			C				Not Reported
	Lopinavir + Ritonavir			C				Not Reported
	Enoxaparin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623633		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Orencia	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Remicade	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Oral			Not Reported
Pennsaid	C				Not Reported
Naproxen Sodium	C	Unknown			Not Reported
Metoprolol	C	Unknown			Not Reported
Macrogol	C				Not Reported
Indomethacin [Indometacin]	C				Not Reported
Folic Acid	C	Unknown			Not Reported
Endocet	C	Unknown			Not Reported
D-Alpha Tocopherol	C	Unknown			Not Reported
Bisoprolol	C	Unknown	Every 1 Days		Not Reported
Asa	C	Unknown			Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown			Not Reported
Fish Oil	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924224	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049375		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Q4wk		Not Reported

Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Codeine	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	1 Every 12 Hours	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	2 Dosage Form, Qd	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	1 Every 1 Days	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Levothyroxine	S	Unknown	1 Dosage Form, Qd	Not Reported
	Levothyroxine Sodium	S	Unknown	1 Every 1 Days	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
	Ramipril	S	Unknown	1 Dosage Form, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1 Every 1 Days	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
	Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Tylenol With Codeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924254	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1788903		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Lopinavir+Ritonavir			S	Oral			Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924802	EXPEDITED (15-DAY)		HO, LT	NVSC2020ES173569		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Qd (2gr/24h)		Not Reported
	Metilprednisolona			S	Intravenous (not otherwise specified)	250 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Q12h (200/50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimidos)		Not Reported
	Dolquine			S	Oral	200 Mg, Q12h (200 Mg Comprimidos Recubiertos,30 Comprimidos)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924864	EXPEDITED (15-DAY)		OT	NVSC2020FR173171		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg J1, Puis 250 Mg (250 Mg, Comprime Pellicule)		Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924874	EXPEDITED (15-DAY)		OT	NVSC2020ES173444		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Azitromicina			S	Oral	500 Mg, Qd (Dia)		Not Reported
	Azitromicina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925119	EXPEDITED (15-DAY)		HO	NVSC2020ES169609		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Hyperbilirubinaemia	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Novartis
	Dolquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd (2 Gr)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925121	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3453226-00		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925135	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049429			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925625	EXPEDITED (15-DAY)		LT	NVSC2020FR173058		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg, Qd		Novartis
	Plaquenil			S	Oral	800 Mg, Qd (Comprimé Pelliculé)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925821	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1789183		69 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia	Hidroxicloroquina Sulfato			S	Oral	400 Mg		Teva

(2143su)					
Azitromicina (7019a)	S	Oral	500 Mg		Not Reported
Interferon Beta-1a (2305ou)	S	Subcutaneous	30 Mcg		Not Reported
Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid	S	Oral	200/50 Mg, 2 Df		Not Reported
Levofloxacino (2791a)	S	Intravenous (not otherwise specified)	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925892	EXPEDITED (15-DAY)		HO	NVSC2020ES173420		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd (Dia)		Not Reported
	Ceftriaxona			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925896	EXPEDITED (15-DAY)		OT	NVSC2020FR173166		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Supraventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1, Puis 250 Mg/Jour (250 Mg, Comprime Pellicule)		Novartis
	Azithromycin			S	Other	250 Mg, Once/Single		Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Plaquenil			S	Other	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925972	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1056837		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Off Label Use	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan
	Tocilizumab			C	Intravenous (not otherwise specified)	800 Milligram, Qd		Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17926581	EXPEDITED (15-DAY)		OT	NVSC2020CA172811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Cosentyx			S	Unknown	150 Mg, Qmo		Novartis
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Cymbalta			C	Oral	60 Mg, Qd		Not Reported
	Esomeprazole Magnesium			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17927427	EXPEDITED (15-DAY)		OT	NVSC2020FR173993			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Intentional Product Use Issue	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Novartis
	Amoxicillin Trihydrate			S	Oral	3 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610762		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928393	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3447971-00		67 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug-Induced Liver Injury; Haemodynamic Instability; Off Label Use	Kaletra			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Clonidine Hcl			S	Intravenous drip	400 Mcg/H/24h		Not Reported
	Clonidine Hcl			S	Oral	150mcg 3x/D And Tapering-Off		Not Reported
	Tazobac			S	Intravenous drip			Not Reported
	Tazobac			S	Intravenous drip			Not Reported
	Fospropofol Sodium			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Co-Amoxicillin			C	Intravenous drip			Not Reported
	Fragmin			C				Not Reported
	Pantozol			C		Morning		Not Reported
	Exforge			C		5mg/80mg Morning		Not Reported
	Ramipril/Amlodipin			C				Not Reported
	Solumedrol			C	Intravenous (not otherwise specified)			Not Reported
	Solumedrol			C	Oral	Tapering Off		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	10296970	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1105839		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthritis; Blood Creatinine Decreased; Blood Creatinine Decreased; Condition Aggravated; Condition	Rituxan			S	Intravenous (not otherwise specified)	First Rpap Dose		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown Dosing Details		Not Reported

Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haematocrit Decreased; Haemoglobin Decreased; Haemoglobin Decreased; Headache; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Lymphocyte Count Increased; Monocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nasopharyngitis; Nausea; Nausea; Neutrophil Count Decreased; Neutrophil Count Decreased; Ocular Procedural Complication; Ocular Procedural Complication; Optic Neuritis; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Tinnitus; Vision Blurred; Vision Blurred; White Blood Cell Count Decreased; White Blood Cell Count Decreased	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	S	Unknown	Once Daily Except Friday	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Discontinued Due To Ophthalmic Problems	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Dilaudid	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Acetaminophen	S	Oral		Not Reported
	Acetaminophen	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	S	Unknown		Not Reported
	Fosavance	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported
	Diphenhydramine Hcl	C	Oral		Not Reported
	Diphenhydramine Hcl	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported

	Hydrocortisone	C	Intravenous (not otherwise specified)		Not Reported
	Humira	C			Not Reported
	Orencia	C			Not Reported
	Remicade	C			Not Reported
	Alendronate Sodium;Colecalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	12856089	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Discontinued Due To A Side Effect For 2 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Discontinued Due To Developing Cancer		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Taken For 2 Years, Stopped Working		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Stopped Working Therapy Duration: 730 Days		Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Minocycline	S	Unknown	Not Reported
Amoxicillin	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Amoxicillin;Clavulanate Potassium	C		Not Reported
Amoxil [Amoxicillin]	C		Not Reported
Adalimumab	C		Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
Bcg Vaccine	C	Unknown	Not Reported
Amoxicillin	C		Not Reported
Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown	Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported
Amoxillat	C		Not Reported
Gold	C	Unknown	Not Reported

	Hydroxychloroquine	C	Subcutaneous	Not Reported
	Risedronate	C	Oral	Not Reported
	Bcg Vaccine	C	Unknown	Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
	Risedronate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	13067408	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1871510		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Oral			Not Reported
	Reactine [Cetirizine			S	Unknown			Not Reported

During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Hydrochloride] Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S			Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Cortisone	S	Unknown		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Not Reported
Topicort [Desoximetasone]	S	Oral	Not Reported

	Topicort [Desoximetasone]	S	Other	Not Reported
	Topicort [Desoximetasone]	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Winpred	S	Unknown	Not Reported
	Tofacitinib Citrate	C		Not Reported
	Salazopyrin	C		Not Reported
	Lisinopril	C		Not Reported
	Ibuprofen	C		Not Reported
	Vitamin D3	C		Not Reported
	Zyrtec-D	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	13663116	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951182		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Tremor	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported

Humira	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Folic Acid	C	Oral	Not Reported
Folic Acid	C	Oral	Not Reported
Pantoprazole	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Oral	Not Reported
Pantoprazole Magnesium	C	Oral	Not Reported
Tenofovir Disoproxil	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Methotrexate	C	Oral	Not Reported
Methotrexate	C	Oral	Not Reported
Methotrexate	C	Oral	Not Reported
Tenofovir	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	14412201	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT007901			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth	Acetylsalicylic Acid			S	Transplacental	Maternal Dose: 100 Mg, Qd		Not Reported

Weight Baby; Neonatal Respiratory Distress Syndrome; Premature Baby	Hydroxychloroquine	S	Transplacental	Maternal Dose: 400 Mg, Qd	Novartis
	Prednisone	S	Transplacental	Maternal Dose: 25 Mg, Qd	Not Reported
	Prednisone	S	Transplacental	Maternal Dose: 7.5 Mg, Qd	Not Reported
	Prednisone	S	Transplacental	Maternal Dose: 10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	15401008	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180913733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Infection; Localised Infection; Pneumonia; Rheumatoid Arthritis; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	7.5 Mg To 22.5 Mg		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Metronidazole			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

Dilaudid	C	Unknown	Not Reported
Risedronate	C	Unknown	Not Reported
Salbutamol	C	Unknown	Not Reported
Nitroglycerin	C	Unknown	Not Reported
Crestor	C	Unknown	Not Reported
Crestor	C	Unknown	Not Reported
Hydromorph	C	Unknown	Not Reported
Januvia	C	Unknown	Not Reported
Pantoloc	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Vitamin D	C	Unknown	Not Reported
Lactobacillus Acidophilus	C	Unknown	Not Reported
Aspirin	C	Unknown	Not Reported
Triamcinolone	C	Intra-articular	Not Reported
Triamcinolone	C	Unknown	Not Reported
Lidocaine	C	Unknown	Not Reported
Kenalog	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Calcium Gluconate	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	15612498	EXPEDITED (15-DAY)		OT	PHHY2018ES109862		22 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oesophageal Candidiasis;	Prednisone			S	Unknown	60 Mg, Qd		Not Reported

Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Prednisone	S	Unknown	2.70 G, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Novartis
	Hydroxychloroquine	S				Novartis
	Imurel	S	Unknown	Unk		Not Reported
	Imurel	S				Not Reported
	Imurel	S				Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	15619748	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555750-00		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	15680306	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575130-00		49 YR	Female	CAN

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

Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Penicillin G	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	15841668	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018134129		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen

Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Celebrex	S	Unknown	Unk	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Pantoprazole	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Clindamycin Hcl	S	Unknown	Unk	Not Reported
	Lopressor	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported

Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Atenolol	C		Unk	Not Reported
Colchicine	C		Unk	Not Reported
Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
Leucovorin [Folinic Acid]	C		Unk	Not Reported
Levothyroxine Sodium	C		Unk	Not Reported
Ranitidine	C		Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Tecta	S	Unknown	Unk	Not Reported
Biaxin Xl	S	Unknown	Unk	Not Reported
Gliclazide	S	Unknown	Unk	Not Reported
Veltassa	C	Unknown	Unk	Not Reported
Venofer	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	15958056	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170820946		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindication To	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Vaccination; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint Swelling; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Simponi	S	Subcutaneous		Janssen
	Simponi	S			Janssen
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Imuran	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Humira	S	Subcutaneous	0.8 Ml	Not Reported
	Humira	S	Subcutaneous	0.8 Ml	Not Reported
	Humira	S	Subcutaneous	0.8 Ml	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Certolizumab	S	Subcutaneous		Not Reported
	Certolizumab	S	Subcutaneous		Not Reported
	Azathioprine	S	Unknown		Not Reported

Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Lyrica	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cellcept /01275102/	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Pregabaline	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16120764	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044085			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Q2wk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Bid	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg, Qd	Not Reported
	Tiaprofenic Acid	C	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine Sulphate	C	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	C	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	C	Subcutaneous	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16160518	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2732377-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16163883	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2733467-00		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16178863	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2738275-00		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16195720	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741762-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rabeprazole Sodium			C				Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16350638	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2793223-00		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Ill-Defined Disorder; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Ulcer	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Losec			C	Unknown			Not Reported

	Synthroid	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Betaloc	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16550964	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2847214-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16657664	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2872151-00		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Rheumatoid Factor Positive; Synovitis; Treatment Failure	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	16837596	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-163-2933512-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia;	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Pneumonia; Rash;
Unevaluable Event;
Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17019442	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457981		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Inability; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Pneumonia; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Zingiber Officinale	C	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Calcium	C		Not Reported
	Ergocalciferol	C		Not Reported
	Tiaprofenic Acid	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17221720	EXPEDITED (15-DAY)		HO	CA-ROCHE-2456725		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	Liquid Also Know As Immune Globulin (Human)		Not Reported
	Gammagard			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Triamcinolone	C	Other	Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17399035	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010345		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Subcutaneous			Not Reported

Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Xeljanz	C	Oral	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17422932	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Gram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17464142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553858			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Tooth Loss	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17466449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551554		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	9.0 Months		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	9.0 Months		Not Reported
	Enbrel			S	Unknown	4.0 Years Therapy Duration:24528.0 Hours		Not Reported
	Humira			S	Subcutaneous	4.0 Years Therapy Duration :1278 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	2.0 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported

Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	2.0 Years Thetrapy Duration : 511 Days	Not Reported
Simponi	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17678919	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004002835			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Renal Impairment; Septic Shock	Hydroxychloroquine			S	Intravenous (not otherwise specified)	600 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17699175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585119		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported

Stiffness; Musculoskeletal Stiffness; Off Label Use; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium	S	Unknown	Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tridural	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Cimetidine	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17722162	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3377866-00		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome; Product Use In Unapproved Indication	Kaletra			S	Oral			Not Reported
	Dolquine			S	Oral	A Compressed Breakfast And Dinner		Not Reported
	Propofol			S	Unknown			Not Reported
	Midazolam			S	Unknown			Not Reported
	Azitromicina			S	Unknown			Not Reported

	Ceftriaxone		S	Unknown		Not Reported
	Simvastatina		C			Not Reported
	Rilast		C		Turbuhaler 160 Mcg/4,5 Mcg /Inhalacion Polvo Para Inhalacion , 1 Inhalador De 120 Dosis	Not Reported
	Manidon		C			Not Reported
	Omnic Ocas		C		0,4 Mg Comprimidos De Liberacion Prolongada Recubiertos Con Pelicula , 30 Comprimidos	Not Reported
	Kalpress		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17727217	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3384129-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Dolquine			S	Oral			Not Reported
	Dolquine			S				Not Reported
	Azitromicina			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17728596	EXPEDITED (15-DAY)		OT	BE-ELI_LILLY_AND_COMPANY-BE202004006858		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Interaction; Electrocardiogram Qt Prolonged	Zyprexa Velotab 5mg			S	Oral	1/2 Tablet 2x/Day		Not Reported
	Zyprexa Velotab 5mg			S	Oral	1/2 Tablet 2x/Day		Not Reported
	Plaquenil S			S	Oral	1 Dosage Form, Bid		Not Reported
	Plaquenil S			S	Oral	1 Dosage Form, Daily		Not Reported

	Trazodone Eg	S	Oral	1/4 Tablet In Morning, At Noon, 1/2 Tablet In Evening,Patient Was Taking This Before Hospitalization	Not Reported
	Algostase Mono	C	Unknown	3 Dosage Form, Daily	Not Reported
	Algostase Mono	C		1 Dosage Form, Tid	Not Reported
	Clexane	C			Not Reported
	Potassium 99	C	Oral	600 Mg, Unknown	Not Reported
	L-Thyroxine Roche	C	Unknown		Not Reported
	L-Thyroxine Roche	C		150 Ug, Daily	Not Reported
	Perindopril	C	Unknown		Not Reported
	Perindopril	C		2 Mg, Daily	Not Reported
	Metformin	C	Unknown		Not Reported
	Metformin	C		500 Mg, Bid	Not Reported
	Movicol Apelsin	C	Unknown		Not Reported
	Prolopa	C	Unknown	0.5 Dosage Form, Daily	Not Reported
	Contramal	C	Unknown	1 Dosage Form, Prn	Not Reported
	Pradaxa	C			Not Reported
	Uni Diamicron	C		60 Mg, Bid	Not Reported
	Magnetop [Magnesium Citrate]	C	Oral	450 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17758054	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437417		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Test Positive	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17765723	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500991		67 YR	Female	CAN

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

Plaquenil /00072602/	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Atorvastatin	C		Not Reported
Bisoprolol	C		Not Reported
Digoxin	C		Not Reported
Folic Acid	C		Not Reported
Furosemide	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Methotrexate	C		Not Reported
Nifedipine	C		Not Reported
Palafer	C		Not Reported
Pantoprazole	C		Not Reported
Plaquenil /00072602/	C		Not Reported
Prednisone	C		Not Reported
Synthroid	C		Not Reported
Toloxin /00017701/	C		Not Reported
Valsartan	C		Not Reported
Vitamin D3	C		Not Reported
Xarelto	C		Not Reported
Xeljanz	C		Not Reported
Zinc Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17805682	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599992		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	D-Alpha Tocopherol	C	Unknown	Not Reported
	Endocet	C	Unknown	Not Reported
	Endocet	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Indomethacin [Indometacin]	C	Unknown	Not Reported
	Macrogol	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Omega-3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C	Unknown	Not Reported
	Naproxen Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17806682	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517486			Male	CAN

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

Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Remicade		S	Intravenous (not otherwise specified)	Janssen
	Tofacitinib		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Tofacitinib Citrate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17810677	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600210		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported

	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17812965	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200515201		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17815323	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602209		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17818429	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Off Label Use; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Celebrex	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17832699	EXPEDITED (15-DAY)		DS, OT	BE-ADVANZ PHARMA-202005005612			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Dizziness; Heart Rate Increased; Off Label Use; Tachycardia; Vertigo	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid (Q12h)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Folic Acid			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Levorichter 30			C		Unk		Not Reported
	Befact			C		Unk		Not Reported
	C-Will			C		Unk		Not Reported
	Foliumzuur			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17837078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605414		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17839405	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3422032-00		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash Morbilliform	Kaletra			S	Oral			Not Reported
	Fidato			S	Intravenous (not otherwise specified)	Fidato 2 G Polvere Per Soluzione Per Infusione		Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Azithromycin			S	Oral			Not Reported
	Urbason			S	Intravenous (not otherwise specified)	Urbason Solubile		Not Reported
	Plaquenil			S	Oral			Not Reported
	Roactemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17840270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605515		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Ibuprofen	C		Not Reported
	Lisinopril	C		Not Reported
	Fosamax	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17847317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607208		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Treatment Failure; Visual Impairment	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Intravenous (not			Not Reported

				otherwise specified)	
	Methotrexate		C	Subcutaneous	Not Reported
	Methotrexate		C	Subcutaneous	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Sulfasalazine		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17856297	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535392		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Intramuscular			Not Reported
	Wellbutrin			C	Unknown	Extended Release Tablet		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17859973	EXPEDITED (15-DAY)		LT	NVSC2020FR155031		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Lasilix			S	Intravenous (not otherwise specified)	2 Df, Qd (20mg/2ml)		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	4 Df, Qd (4g/500mg)		Not Reported
	Transipeg			C	Oral	Unk		Not Reported
	Potassium			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Nimbex			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Effexor			C	Oral	Unk		Not Reported
	Ultibro Breezhaler			C	Respiratory (inhalation)	Unk		Not Reported
	Seresta			C	Oral	Unk		Not Reported
	Rocephine			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17861661	EXPEDITED (15-DAY)		HO	NVSC2020ES155013		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Coronavirus Infection; Diarrhoea; Febrile Neutropenia; Febrile Neutropenia; Fusobacterium Infection; Mucosal Inflammation; Nausea	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Novartis
	Carboplatin			S	Unknown	750 Day 1/3 Weeks		Not Reported
	Carboplatin			S	Unknown	360, 1/3 Weeks		Not Reported
	Carboplatin			S	Other	600 Day 1/3 Weeks		Not Reported
	Etoposide			S	Unknown	213, Day 1,2,3 3weeks		Not Reported
	Etoposide			S	Unknown	213, Day 1,2,3 3weeks		Not Reported
	Etoposide			S	Unknown	165, Day 1,2,3 3weeks		Not Reported
	Nivolumab			S	Unknown	360, 1/3 Weeks		Not Reported
	Nivolumab			S	Unknown	360, 1/3 Weeks		Not Reported
	Nivolumab			S	Unknown	360, 1/3 Weeks		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	125 Mg		Not Reported
	Tazobactam			C	Unknown	Unk		Not Reported
	Tazobactam			C	Unknown			Not Reported
	Piperacillin			C	Unknown	Unk		Not Reported
	Ciprofloxacin			C	Unknown	Unk		Not Reported
	Metronidazole			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Quetiapine			C	Unknown	50 Mg		Not Reported
	Buscapina			C	Unknown	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17883041	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005006118			Unknown	CAN

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

Diarrhoea; Dizziness; Drug Intolerance; Ocular Toxicity	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Concordia
	Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
	Methotrexate	C		Unk	Not Reported
	Enbrel	C		Unk	Not Reported
	Orencia	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17907407	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1787868		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400mg Every 12 Hours Followed By 200mg Every 12 Hours, Unit Dose: 1 Df Hidroxicloroquina (2143a)		Teva
	Hydroxychloroquine Sulfate			S				Teva
	Accord Lopinavir W/Ritonavir			S	Oral	2 Df Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con Pelicula Efg , 120 Comprim		Not Reported
	Accord Lopinavir W/Ritonavir			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 G		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926160	EXPEDITED (15-DAY)		OT	BE-ACCORD-182154		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Trazodone/Trazodone Hydrochloride			S		1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The Evening		Not Reported

	Zyprexa	S	Oral	1/2 Tablet 2x/Day Treatment Was Suspended	Not Reported
	Plaquenil	S	Oral	Day 1: 400mg 2x/D Day 2-4: 200mg 1x/D	Not Reported
	Prolopa	C		0.5 Df, Qd	Not Reported
	Algostase Mono	C		1 Df, Tid	Not Reported
	Contramal	C		Unk Unk, Prn	Not Reported
	Pradaxa	C			Not Reported
	Movicol	C		1 Df, Qd	Not Reported
	Uni Diamicron	C		60 Mg, Bid	Not Reported
	Levothyroxine	C		150 Ug, Qd	Not Reported
	Metformin	C		500 Mg, Bid	Not Reported
	Magnetop	C	Oral	450 Mg, Qd	Not Reported
	Clexane	C			Not Reported
	Perindopril	C		2 Mg, Qd	Not Reported
	Kalium	C	Oral	600 Mg	Not Reported
	Trazodone/Trazodone Hydrochloride	S			Not Reported
	Zyprexa	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926169	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624780		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926546	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-250917		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder	Azithromycin			S	Oral	Unk		Sun
	Hidroxicloroquina Sulfato (2143su)			S	Oral	Unk		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			S	Oral	2 Dosage Form, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926584	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-251089		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Milligram, Q3h		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	100 Milligram, Daily		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Sun
	Hydroxychloroquine			S	Oral	400 Milligram, Daily		Sun
	Furosemide			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926586	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-250919		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azithromycin			S	Oral	Unk		Sun
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			S	Oral	2 Dosage Form, Bid		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926606	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-250355		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Nausea; Quadriparesis; Somnolence; Suicide Attempt; Toxicity To Various Agents; Ventricular Tachycardia; Vomiting	Hydroxychloroquine			S	Unknown	20 Tablet, Unk		Sun
	Methotrexate			S	Unknown	30 Tablets, Unk		Sun
	Prednisone			S	Unknown	30 Tablets, Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926612	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251238		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	()		Sun

	Ceftriaxona	S	Intravenous (not otherwise specified)	()		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...	S	Oral			Not Reported
	Hidroxicloroquina Sulfato (2143su)	S	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17926843	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-250433		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertension; Off Label Use; Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Ipca
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17927966	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3451853-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17927973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624564		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Salazopyrina			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Align			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928106	EXPEDITED (15-DAY)		OT	CA-ROCHE-2625514			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Rituximab			S	Intravenous drip			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Sulfate]			
Piperacilline / Tazobactam	S	Unknown	Not Reported
Mycophenolic Acid	S	Unknown	Not Reported
Lasix [Furosemide]	S	Unknown	Not Reported
Ceftazidime	S	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Slow K	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported
Risedron	C	Unknown	Not Reported
Potassium Chloride	C	Unknown	Not Reported
Piperacilina + Tazobactam	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Metoprolol	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Januvia [Sitagliptin]	C	Unknown	Not Reported
Insulin Lispro	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Escitalopram	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Amiodarone Hydrochloride	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Ventolin [Salbutamol]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2627287		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Blood Pressure	Rituximab			S	Intravenous (not			Not Reported

Systolic Increased; Cataract; Decreased Appetite; Dizziness; Dyspepsia; Heart Rate Decreased; Nausea; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased				otherwise specified)	
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Acetaminophen		C	Oral	Not Reported
	Atorvastatin		C	Unknown	Not Reported
	Cymbalta		C		Not Reported
	Hydroxychloroquine		C		Not Reported
	Irbesartan		C		Not Reported
	Lipitor		C	Unknown	Not Reported
	Prednisone		C		Not Reported
	Solu-Medrol		C	Intravenous (not otherwise specified)	Not Reported
	Tramadol		C	Unknown	Not Reported
	Vitamin D3		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928305	EXPEDITED (15-DAY)		OT	NVSC2020CA172682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Cosentyx			S	Oral	300 Mg, Qmo		Novartis
	Diclofenac			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Pantoprazole			S	Oral	1 Df, Qd		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Leucovorin Calcium			S	Oral	5 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

Golimumab	S	Unknown	Unk		Not Reported
Meloxicam	S	Oral	7.5 Mg, Qd		Not Reported
Diltiazem Hydrochloride	C	Oral	240 Mg, Unknown		Not Reported
Fluticasone Propionate	C	Respiratory (inhalation)	Unk		Not Reported
Mar-Pantoprazole	C	Unknown	Unk		Not Reported
Mometasone Furoate	C	Unknown	Unk		Not Reported
Premarin	C	Unknown	Unk		Not Reported
Salbutamol	C	Unknown	Unk		Not Reported
Tramadol Hydrochloride	C	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928403	EXPEDITED (15-DAY)		HO	NVSC2020ES173059		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatocellular Injury	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Azithromycin			S				Novartis
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone			S				Not Reported
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928445	EXPEDITED (15-DAY)		OT	CA-ACCORD-185900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported

Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928458	EXPEDITED (15-DAY)		DE, OT	NVSC2020DE174795		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Compartment Syndrome; Acute Respiratory Distress Syndrome; Drug Ineffective; Haemophagocytic Lymphohistiocytosis; Pancreatitis Necrotising; Sepsis; Shock Haemorrhagic; Withdrawal Syndrome	Prednisolone			S	Unknown	Unk, Pulse Therapy		Novartis
	Prednisolone			S	Oral	Unk, >20mg/Day		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928470	EXPEDITED (15-DAY)		OT	CA-ACCORD-185839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17928637	EXPEDITED (15-DAY)		HO	CA-ROCHE-2625364			Female	CAN

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

Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Rituximab	S	Intravenous drip	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17929306	EXPEDITED (15-DAY)		OT	NVSC2020FR173175		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycine Sandoz 250 Mg Filmomhulde Tabletten			S	Oral	500 Mg(J1, Puis 250 Mg/Jour)		Novartis
	Azithromycine Sandoz 250 Mg Filmomhulde Tabletten			S	Other	250 Mg, Qd		Novartis
	Plaquenil			S	Unknown	600 Mg, Qd		Not Reported
	Plaquenil			S	Other	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17929320	EXPEDITED (15-DAY)		OT	NVSC2020US173860			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17929405	NON-EXPEDITED			US-ADVANZ PHARMA-202006006441			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17929445	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202006006473			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage; Metastases To Eye; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Depakote			S	Unknown	Unk		Not Reported
	Depakote			S				Not Reported
	Imovane			S	Unknown	3.75 Mg		Not Reported
	Plavix			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17929903	EXPEDITED (15-DAY)		OT	CA-ACCORD-186223		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Off Label Use; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate			S	Oral			Accord
	Rosuvastatin			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930041	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202006006538			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930063	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202006006559			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930094	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-19998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unknown		Not Reported
	Diclofenac			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown	Unknown		Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

Cimzia	S	Subcutaneous	Unknown		Not Reported
Humira	S	Subcutaneous	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930153	EXPEDITED (15-DAY)		OT	ES-ASTELLAS-2020US020851		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury; Product Use In Unapproved Indication	Micafungin			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Azithromycin			S	Oral			Not Reported
	Sulfamethoxazole+Trimethoprim			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Kaletra			S	Oral	2 Df, Once Daily (200/50 Mg, Film Coted Tablets)		Not Reported
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930185	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623437		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia;	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported

Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Asa		S	Unknown	Not Reported
	Calcium Carbonate		S	Unknown	Not Reported
	Fosinopril		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Morphine Sulfate		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Synthroid		S	Unknown	Not Reported
	Vitamin D [Colecalciferol]		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930257	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1789660		76 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	200 Mg (1-0-0,5); Unit Dose: 300 Mg		Teva
	Imurel 50 Mg Comprimidos Recubiertos Con Pelicula , 50 Comprimidos			S	Oral	50 Milligram Daily; 1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930348	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1789661		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930417	EXPEDITED (15-DAY)		DE, HO	IT-PFIZER INC-		78 YR	Female	ITA

2020238831

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Doxycycline Hyclate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Cobicistat/Darunavir			S		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930671	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201807-002605			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Capsule Opacification; Rhinitis Allergic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd Unk X 1 Days		Concordia
	Edirol			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Pariet			C		Unk		Not Reported
	Prograf			C		Unk		Not Reported
	Benet			C		Unk		Not Reported
	Loxonin			C		Unk		Not Reported
	Magmitt			C		Unk		Not Reported
	Azilva			C		Unk		Not Reported
	Rinderon-Vg			C		Unk		Not Reported
	Hirudoid			C		Unk		Not Reported
	Rosuvastatin Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930687	EXPEDITED (15-DAY)		HO	NVSC2020IT174298		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Piperacillin Sodium,Tazobactam Sodium			S	Intravenous (not otherwise specified)			Novartis
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Kaletra			S	Oral	4 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2626485		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Hepatic Cirrhosis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Escitalopram Oxalate			C				Not Reported
	Furosemide			C				Not Reported
	Pantoprazole			C				Not Reported
	Perindopril			C				Not Reported
	Prednisone			C				Not Reported
	Spironolactone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930922	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1056849		69 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan
	Levofloxacino /01278901/			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Mylan
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan
	Interferon Beta-1b			S	Subcutaneous	30 Microgram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931128	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505925		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Sulfadiazine			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Naproxen			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Calcium Carbonate			C	Oral			Not Reported
	Folic Acid			C	Unknown	1 Dosage Form		Not Reported
	Hydromorphone			C	Oral			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Vitamin D /00107901/			C	Oral	1000 Mg And 2000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931191	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	22 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931205	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20200624035			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use; Product Use In Unapproved Indication	Prezista			S	Oral			Janssen
	Ritonavir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931310	EXPEDITED (15-DAY)		OT	NVSC2020ES172767		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt	Venlafaxine			S	Unknown	225 Mg, Q24h		Not Reported

Prolonged; Product Use In Unapproved Indication	Lopinavir,Ritonavir		S	Unknown	Unk, Q12h	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Q24h	Novartis
	Azithromycin		S	Unknown	250 Mg, Q24h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931333	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3449706-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hip Arthroplasty; Latent Tuberculosis; Osteoarthritis; Pain; Rash; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rinvoq			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Baricitinib			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931414	EXPEDITED (15-DAY)		HO	NVSC2020ES173156		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg, Qd (500mg Dia)		Novartis
	Dolquine			S	Oral	400 Mg, Qd (400 Mg Dia 200 Mg Comprimidos Recubiertos, 30 Comprimidos)		Not Reported
	Kaletra			S	Oral	2 Df, Q12h (2u / 12h 200/50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimidos)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931458	EXPEDITED (15-DAY)		OT	NVSC2020IT173769		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral			Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931459	EXPEDITED (15-DAY)		OT	NVSC2020ES174583		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Ageusia; Anosmia; Condition Aggravated; Nausea; Off Label Use; Oxygen Saturation; Productive Cough; Pyrexia	Ceftriaxone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Methylprednisolone			C	Unknown	60 Mg		Not Reported
	Tocilizumab			C	Unknown	600 Mg		Not Reported
	Heparin			C	Unknown	Prophylactic Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17932159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17932465	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020240541		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17933011	EXPEDITED (15-DAY)		DE, OT	ES-BIOGEN-2020BI00887781		69 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Hyperbilirubinaemia; Off Label Use	Avonex			S	Subcutaneous	1 Days		Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Avonex			S				Biogen
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Levofloxacin			S	Intravenous (not otherwise specified)	1 Days		Not Reported
	Azithromycin			S	Oral	1 Days		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			S	Oral	1 Days		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17933054	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA170829		62 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	1 Df, Qw		Not Reported
	Sulfasalazine			S	Oral	2 G (1 Every 1 Days)		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Tramacet			S	Oral	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Oxycodone Hcl			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1.0 Mg		Not Reported
	Metformin			C	Unknown	5.0 Mg		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

Premaril	C	Unknown	0.625 Mg		Not Reported
Risedronate Sodium	C	Unknown	35.0 Mg		Not Reported
Vagifem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17933482	EXPEDITED (15-DAY)		HO	NVSC2020ES171718		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azitromicina			S	Oral	500 Mg, Qd (Dia)		Novartis
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	Unk Unk, Q24h (C/24 H, Vial)		Not Reported
	Ertapenem			S	Intravenous (not otherwise specified)	1 G, Qd (1 G Dia)		Not Reported
	Dolquine			S	Oral	400 Mg, Qd (30 Comprimidos) (Dia)		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17933684	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17933887	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012554			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	13123418	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1843560-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Operation; Pain; Peripheral Swelling; Rash; Surgery; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Gold	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Rocuronium	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfa	S	Unknown		Not Reported
	Penicillin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Rocuronium Bromide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	13191146	EXPEDITED (15-DAY)		DS	CA-ROCHE-1888720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Indometacin			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	Frequency: Every 1 Day		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

	Gold (198 Au) Colloidal			S	Unknown					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Indocid [Indometacin]			S	Unknown					Not Reported
	Leflunomide			S	Unknown					Not Reported
	Methotrexate			S	Oral					Not Reported
	Methotrexate			S	Subcutaneous					Not Reported
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Cymbalta			C	Oral					Not Reported
	Folic Acid			C	Oral					Not Reported
	Xeljanz			C	Oral					Not Reported
	Ciprodex [Ciprofloxacin Hydrochloride;Dexamethasone]			C	Oral					Not Reported
	Fish Oil			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	13266763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897125			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Feeding Disorder; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Stomatitis;	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Champix			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Weight Decreased	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Varenicline Tartrate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Valacyclovir [Valaciclovir]	C		Not Reported
	Vimovo	C		Not Reported
	Crestor	C		Not Reported
	Oxycocet	C	Oral	Not Reported
	Xeljanz	C		Not Reported
	Acetaminophen	C		Not Reported
	Naproxen	C		Not Reported
	Oxycodone Hydrochloride	C		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
	Prednisone	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Valtrex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	13676283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP013040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Methotrexate			S	Intramuscular	25 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported

Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd		Not Reported
Arava	S	Oral	10 Mg, Qd		Not Reported
Arava	S	Oral	10 Mg, Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	1000 Mg, Once Every Month		Not Reported
Actemra	S	Intravenous (not otherwise specified)	4-8 Mg Per Kg Monthly		Not Reported
Ramipril	C	Unknown	Unk		Not Reported
Asa	C	Unknown	81 Mg, Unk		Not Reported
Metformin	C	Unknown	Unk		Not Reported
Lantus	C	Subcutaneous	Unk		Not Reported
Vitamin D /00107901/	C	Unknown	Unk		Not Reported
Calcium	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Lozide /00340101/	C	Unknown	Unk		Not Reported
Naprosyn /00256201/	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Asa Arthritis Strength Aspirin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	13939347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017491		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective For Unapproved Indication; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Tylenol /00020001/			C	Unknown	Unk, Prn		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	14663290	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007993		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	2.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Folic Acid			C	Oral	2.5 Mg, Qd		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, Qd		Not Reported
	Tenofovir Disoproxil			C	Unknown	Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral	300 Mg, Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	14746073	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	14746233	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown			Apotex
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	14921584	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044591			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	160 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15009839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2137691		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown	Therapy Duration: 2.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3.0 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Orencia			C	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15153599	EXPEDITED (15-DAY)		HO, OT	PHHY2018GR042310		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment;	Prednisolone			S	Unknown	10 Mg, Qd		Novartis
	Prednisolone			S	Unknown	7.5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Folate			S	Unknown	5 Mg, Qw		Not Reported
	Citalopram			C	Unknown	Unk		Not Reported

Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Adalimumab	C	Unknown	Unk		Not Reported
	Alprazolam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15622307	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557499-00		60 YR	Female	CAN

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

	Apo Hydroxyquine	S	Unknown		Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Bupropion	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15622519	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557164-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Tremor	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S				Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Enteric Coated		Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C			Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole Bluefish	C			Not Reported
	Tenofovir Disoproxil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15625429	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557490-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported
	Plaquenil			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported
	Benadryl			C				Not Reported
	Reactine			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15635110	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105549			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone			S	Oral	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4 Every 1 Week		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported
	Infliximab			S	Unknown	5 Mg, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qwk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15635193	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105819			Female	CAN

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

Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral		Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	25 Mg, Qwk	Not Reported
	Prednisone	C	Unknown	30 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	15681461	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575030-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Orencia	C		Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	16108289	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2709179-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Eye Disorder; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia;	Humira			S	Subcutaneous			Not Reported
	Bactrim			S	Oral	160/800 Mg		Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Azathioprine Sodium			S	Oral			Not Reported

Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	16388586	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-029930		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronic Acid Tablets			S	Oral	70 Milligram, Every Week		Aurobindo
	Alendronic Acid			S	Unknown	70 Milligram, 1 Every Week		Aurobindo
	Atorvastatin			S	Unknown	10 Microgram, Once A Day		Not Reported
	Metformin			S	Oral	500 Milligram, Two Times A Day		Aurobindo
	Metformin			S	Unknown	1000 Milligram		Aurobindo
	Omeprazole			S	Oral	20 Milligram		Aurobindo
	Combivent			S	Unknown	Unk		Not Reported
	Flovent			S	Unknown	Unk		Not Reported
	Lasix			S	Unknown	40 Milligram		Not Reported
	Nitrazadon			S	Unknown	10 Milligram, Once A Day		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	500 Milligram, Once A Day		Not Reported
	Losec			S	Oral	20 Milligram, Once A Day		Not Reported
	Losec			S	Oral	20 Milligram		Not Reported
	Liptor			S	Unknown	10 Milligram, Once A Day		Not Reported
	Ipratropium Bromide;Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Atrovent			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	16830284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2644831-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	16855395	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2939258-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral	Therapy Duration 677		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17002427	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-E2B_00008027			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Hydroxychloroquine Sulfate		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unknown		Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Methotrexate Bellon			S	Subcutaneous	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown Iv Nos,		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown,Prefilled Syringe		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17183764	EXPEDITED (15-DAY)		DE, DS	CA-DRREDDYS-USA/CAN/19/0117587		75 YR	Female	CAN

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

Chest Discomfort	Atorvastatin		S	Oral	Not Reported
	Alendronate Sodium		S	Unknown	Not Reported
	Flovent		S	Unknown	Not Reported
	Ipratropium Bromide/Salbutamol Sulfate		S	Unknown	Not Reported
	Lasix		S	Unknown	Not Reported
	Metformin		S	Unknown	Not Reported
	Nitrazadon		S	Oral	Not Reported
	Losec		S	Oral	Not Reported
	Plaquenil		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Salmeterol Xinafoate		S	Unknown	Not Reported
	Tylenol		S	Unknown	Not Reported
	Atrovent		S	Unknown	Not Reported
	Furosemide		S	Unknown	Not Reported
	Lipitor		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17359581	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2543863-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Pruritus; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17412387	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17424444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous		Not Reported
Sirukumab	S	Unknown		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Morphine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Cosentyx	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Dilaudid	C	Unknown		Not Reported
Wellbutrin	C	Unknown	(Extended Release)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17440774	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2018AP013701		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity;	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex

Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S				Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Arava	S				Not Reported
Xeljanz	S	Oral	1 Df, Bid		Not Reported
Cannabis Sativa	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Rituximab	S				Not Reported
Rituximab	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	Unk, Bid		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17717380	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2020FI113463		7 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pleurisy; Pneumonia; Product Use In Unapproved Indication; Respiratory Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17780500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated	Rituximab			S	Intravenous drip			Not Reported

Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17806269	EXPEDITED (15-DAY)		LT	CA-ROCHE-2600489		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Dysphonia; Dyspnoea; Intentional Product Use Issue; Odynophagia; Off Label Use; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17808017	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599400		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Back Pain; Body Temperature Increased; Diarrhoea; Ear Pain; Headache; Insomnia; Joint Swelling; Lower Respiratory Tract Infection; Muscle Spasticity; Night Sweats; Off Label Use; Pain; Peripheral Swelling; Product Use In Unapproved Indication; Pruritus; Rash; Respiratory Disorder; Sinusitis; Urticaria; Vomiting	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Oxycodone And Acetaminophen			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Chloraprep			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Chlorhexidine			S	Unknown			Not Reported
	Chlorhexidine Gluconate			S	Unknown			Not Reported
	Oxycodone Terephthalate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Ubidecarenone			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Desogestrel And Ethinylestradiol			C				Not Reported
	Ergocalciferol			C				Not Reported
	Fish Oil			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Hydroxychloroquine Sulphate			C				Not Reported
	Ibuprofen			C				Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
	Prednisone			C				Not Reported

	Ventolin [Salbutamol]	C	Not Reported
	Vitamin C [Ascorbic Acid]	C	Not Reported
	Vitamin D 3	C	Not Reported
	Zopiclone	C	Not Reported
	Cholecalciferol	C	Not Reported
	Tylenol	C	Not Reported
	Pantoprazole	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17810690	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Actemra	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C		Not Reported
	Meloxicam	C	Unknown	Not Reported
	Acetaminophen And Codeine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17819398	EXPEDITED (15-DAY)		HO	NVSC2020FR138786		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Oral Blood Blister; Pruritus; Purpura; Stress; Thrombocytopenia	Azithromycin Monohydrate			S	Oral	500 Mg, Qd		Novartis
	Azithromycin			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17835087	EXPEDITED (15-DAY)		CA, HO, OT	CA-JNJFOC-20200528676		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Varicella-Zoster Immune Globulin			S	Intramuscular			Not Reported

Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Plaquenil		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17840309	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1241349		84 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Hepatic Function Abnormal	Hydroxychloroquine			S	Oral	200mg Bid, 400 Mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17841450	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1241324		59 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Hepatic Function Abnormal	Hydroxychloroquine			S	Oral	200 Mg Bid. Unit Dose: 400 Mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17843214	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606426			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Burning Sensation; C-Reactive Protein Increased; Colitis; Diarrhoea; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17857394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17860556	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020215876		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk, Every 48 Hours		Pfizer
	Methylprednisolone Sodium Succinate			S		Unk		Pfizer
	Kaletra			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17861385	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2020-FR-1241998		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bundle Branch Block; Conduction Disorder; Decreased Appetite; Drug Ineffective; Dysphagia; Dysphonia; Left Ventricular Hypertrophy; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Weight Decreased	Fenofibrate			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown	400mg Per Day 7.4 Mg/Kg/Day		Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Clobetasol			C	Unknown	1 Application/Day		Not Reported
	Tramadol/Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17873513	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043599			Female	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	40 Milligram		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17885422	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2020026782			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash; Rash	Levofloxacin			S	Oral	1 Dosage Form, Qd		Macleods
	Lopinavir/Ritonavir			S	Oral	4 Dosage Form, Qd		Macleods
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17887436	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043822			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported

Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Infliximab	S	Unknown	5 Milligram		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	(Iv) 3 Milligram, Qwk		Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Kilogram, Qwk		Not Reported
	Naproxen Sodium	S	Unknown			Not Reported
	Prednisone	S	Oral	5 Milligram, Bid		Not Reported
	Prednisone	S	Oral	3 Milligram, Bid		Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Triamcinolone	S	Unknown			Not Reported
	Apo-Naproxen	S	Unknown	Unk		Not Reported
	Apo-Prednisone	S	Oral	5.0 Milligram, Bid		Not Reported
	Apo-Prednisone	S	Oral	3.0 Milligram, Bid		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17888127	EXPEDITED (15-DAY)		OT	IT-ROCHE-2617048		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Intentional Product Use Issue; Off Label Use	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Lopinavir;Ritonavir			S	Oral			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported

	Heparin	C	Unknown	Not Reported
	Magnesium Sulfate	C	Intravenous (not otherwise specified)	Not Reported
	Clindamicina Fosfato	C	Unknown	Not Reported
	Lasix [Furosemide]	C	Intravenous (not otherwise specified)	Not Reported
	Ceftriaxone Disodium	C	Unknown	Not Reported
	Kayexalate	C	Oral	Not Reported
	Urbason [Methylprednisolone Sodium Succinate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17898781	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-028900		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azithromycin			S	Unknown	500 Milligram, One Day 1		Aurobindo
	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Hydroxychloroquine			S	Oral	200 Milligram, 3 Times A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17901397	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200614411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Pertussis Vaccine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Acetylsalicylic Acid	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17931844	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1789670		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Levofloxacino (2791a)			S	Oral	500 Mg		Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Df		Not Reported
	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Novorapid 100 U/Ml Solucion Inyectable En Vial, 1 Vial De 10 Ml			C	Subcutaneous	10 Iu		Not Reported

Oseltamivir (2885a)	C	Oral	75 Mg		Not Reported
Piperacilina + Tazobactam	C	Intravenous (not otherwise specified)	1 Df		Not Reported
Tocilizumab (8289a)	C	Intravenous (not otherwise specified)	600 Mg		Not Reported
Losartan (7157a)	C	Oral	50 Mg		Not Reported
Enoxaparina Sodica (2482so)	C	Subcutaneous	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17931966	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-250969		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia	Azithromycin			S	Unknown	()		Sun
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Co...			S	Oral	400 Mg C/12 Hours		Not Reported
	Hidroxicloroquina (2143a)			S	Unknown	()		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 G Every 24 H		Not Reported
	Optovite B12 1.000 Microgramos Solucion Inyectable			C	Unknown			Not Reported
	Bufomix Easyhaler 320 Microgramos//9 Microgramos/Inhalacion Polvo P...			C	Unknown			Not Reported
	Paracetamol (12a)			C	Unknown			Not Reported
	Condrosan 400 Mg Capsulas Duras			C	Unknown			Not Reported
	Vesicare 5 Mg Comprimidos Recubiertos Con Pelicula			C	Unknown			Not Reported
	Prednisona (886a)			C	Unknown			Not Reported
	Alprazolam 2 Mg Comprimido			C	Unknown			Not Reported
	Axiago 20 Mg Comprimidos Gastrorresistentes			C	Unknown			Not Reported

Atorvastatina 20 Mg Comprimido	C	Unknown	Not Reported
Lyrica 150 Mg Capsulas Duras	C	Unknown	Not Reported
Clexane	C	Unknown	Not Reported
Lorazepam 5 Mg Comprimido	C	Unknown	Not Reported
Sintrom 4 Mg Comprimidos	C	Unknown	Not Reported
Movalis 15 Mg Capsulas	C	Unknown	Not Reported
Doclis Retard 120 Mg Capsulas Duras De Liberacion Prolongada	C	Unknown	Not Reported
Rivotril 2 Mg Comprimidos	C	Unknown	Not Reported
Montelukast 10 Mg Comprimido	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17931981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atenolol			C				Not Reported
	Celebrex			C				Not Reported
	Colchicine			C				Not Reported
	Perindopril			C				Not Reported
	Hctz			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Methotrexate			C				Not Reported
	Calcium Folinate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932105	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Oxycontin			S	Unknown	Unk		Not Reported
	Vitamine B1			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 3 Weeks		Not Reported
	Sulfasalazine			S	Oral	2 Gram, Once A Day		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Celebrex			S	Occlusive dressing technique	Unk		Not Reported
	Aclasta			C	Unknown	Unk		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Biotin			C	Unknown	Unk		Not Reported
	Cholecalciferol			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported

Ferrous Fumarate	C	Unknown	Unk		Not Reported
Ferrous Gluconate	C	Unknown	Unk		Not Reported
Lomotil	C	Unknown	Unk		Not Reported
Loperamide	C	Unknown	Unk		Not Reported
Nasonex	C	Unknown	Unk		Not Reported
Nicotinamide	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Retinol Palmitate	C	Unknown	Unk		Not Reported
Riboflavin	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Unknown	Unk		Not Reported
Thiamine Hydrochloride	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Vitamin A	C	Unknown	Unk		Not Reported
Vitamin B6	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Vitamin C	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932223	EXPEDITED (15-DAY)		LT, OT	ES-AUROBINDO-AUR-APL-2020-029998		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Disorientation; Hyperbilirubinaemia; Liver Function Test Abnormal; Urinary Retention	Levofloxacin			S	Unknown	Unk,500 Mg / 12 Drops		Aurobindo
	Hydroxychloroquine			S	Oral	Unk,800 Mg 1 Dia + 400 Mg El Resto		Not Reported
	Lopinavir;Ritonavir			S	Unknown	Unk,200/20 Four Times A Day		Not Reported
	Omeprazole			C	Unknown	Unk,1/24		Not Reported
	Clexane			C	Unknown	Unk,40/24 Horas		Not Reported

Pulmicort	C	Unknown	Unk,2 Puff Every 8 Hours		Not Reported
Ventolin	C	Unknown	Unk		Not Reported
Urbason	C	Unknown	Unk,40 Mg First Every 8 Hours, At 5 Days Every 12		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932231	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932262	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047736			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Oral			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid		Not Reported
Rituximab	S	Unknown			Not Reported
Vioxx	S	Unknown			Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932288	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047702		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932453	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251216		52 YR	Male	ESP

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

Acute Kidney Injury; Rhabdomyolysis	Azithromycin		S	Oral	Unk	Sun
	Hidroxicloroquina Sulfato (2143su)		S	Oral	Unk	Not Reported
	Ceftriaxona (501a)		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...		S	Oral	2 Dosage Form, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932461	EXPEDITED (15-DAY)		HO	CA-ROCHE-2626143		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Arthralgia; Chills; Diarrhoea; Drug Ineffective; Fatigue; Heart Rate Increased; Liver Function Test Increased; Nausea; Ovarian Cyst; Ovulation Pain; Pain; Pyrexia; Quality Of Life Decreased; Rash; Uterine Cyst; Vomiting; Wheelchair User; White Blood Cell Count Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Cimzia			C				Not Reported
	Cortisone			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932568	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	420 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932606	EXPEDITED (15-DAY)		OT	CA-ROCHE-2625412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported

Humira	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932868	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Discomfort; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported

	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932872	EXPEDITED (15-DAY)		LT	CA-ROCHE-2625418		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Iron Decreased; Blood Pressure Increased; Headache; Interstitial Lung Disease; Joint Swelling; Monocyte Count Increased; Muscle Spasms; Osteoporosis; Oxygen Saturation Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Walking Aid User	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Accupril			C				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Apo-Atorvastatin			C				Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Apo-Zopiclone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Gabapentin			C				Not Reported
	Lactaid			C				Not Reported
	Lactulose			C				Not Reported
	Levemir			C				Not Reported
	Methadone			C				Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Nabilone			C				Not Reported
	Novorapid			C				Not Reported
	Pantoprazole			C				Not Reported
	Pms-Cetirizine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932944	EXPEDITED (15-DAY)		HO	CA-ROCHE-2621183		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Mycophenolate Mofetil			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Bumetanide			S	Unknown			Not Reported
	Capsaicin			S	Topical			Not Reported
	Cimetidine			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Diltiazem			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibudilast			S	Unknown			Not Reported
	Ketamine			S	Intravenous (not otherwise specified)			Not Reported
	Ketamine			S	Topical			Not Reported
	Ketamine			S	Oral			Not Reported
	Lidocaine			S	Intravenous (not otherwise specified)			Not Reported
	Lidocaine			S	Topical			Not Reported
	Lithium Carbonate			S	Unknown			Not Reported
	Magnesium			S	Unknown			Not Reported
	Magnesium			S				Not Reported
	Memantine			S	Unknown			Not Reported
	Metprolol			S	Unknown			Not Reported
	Mexiletine			S	Unknown			Not Reported
	Montelukast			S	Unknown			Not Reported
	N-Acetylcysteine			S	Unknown			Not Reported
	Naltrexone Hydrochloride			S	Unknown			Not Reported

	Palmitoylethanolamide	S	Unknown	Not Reported
	Pentoxifylline	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Spironolactone	S	Unknown	Not Reported
	Vitamin B2 [Riboflavin]	S	Unknown	Not Reported
	Vitamin C [Ascorbic Acid]	S	Unknown	Not Reported
	Calcitonin	C	Unknown	Not Reported
	Ezetimibe	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932956	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251159		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Co...			S	Oral	2 Dosage Form, Bid		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400mg C/12 Horas Seguido De 200mg C/12 Horas		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932969	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047622		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Normal; Restless Legs Syndrome	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17933291	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Folic Acid			C	Oral	0.5 Milligram		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17933361	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17933382	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019226		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Arthralgia; Diarrhoea	Leflunomide			S	Oral	20 Mg, Qd (Daily)		Apotex
	Leflunomide			S	Oral	20 Mg, Q.O.D.		Apotex
	Leflunomide			S	Oral	20 Mg, Daily		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported

	Methotrexate		S	Subcutaneous	25 Mg, Unk	Not Reported
	Hydroxychloroquine		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17933625	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02948		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17933674	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02950		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Tocilizumab			C	Unknown	400 Milligram, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17933733	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251405		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Unknown	()		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram, Daily		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			S	Oral	4 Dosage Form, Daily		Not Reported
	Ceftriaxona (501a)			S	Unknown	()		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17933736	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251403		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Unknown	()		Sun
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	()		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram, Daily		Not Reported
	Ceftriaxona (501a)			S	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934022	EXPEDITED (15-DAY)		HO	CA-ROCHE-2624909		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Azathioprine			C				Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Glyburide			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Pariet			C				Not Reported
	Ramipril			C				Not Reported

Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Synthroid	C	Not Reported
	Trajenta	C	Not Reported
	Vitamin B6	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934238	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623739		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Off Label Use; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral	6 Years		Not Reported
	Methotrexate			S	Oral	140 Days		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Allopurinol	C	Unknown	Not Reported
	Cephalexin Monohydrate	C	Unknown	Not Reported
	Cefalexin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934280	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048320			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram (1 Every 1 Month)		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qw (1 Every 1 Week)		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Od		Not Reported
	Methotrexate			S	Unknown	1 Dosage Form, Qw		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram (1 Every 1 Month)		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2.5 Milligram, Od		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Lomotil /00034001/			C	Unknown	Unk		Not Reported

Loperamide	C	Unknown	Unk		Not Reported
Nasonex	C	Unknown	Unk		Not Reported
Oxycodone	C	Unknown	Unk		Not Reported
Pantoprazole Magnesium	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048054			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	1.2 Milliliter		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934299	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048124		40 YR	Male	CAN

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

Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Unknown	Bristol Myers Squibb
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934457	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623456		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Intentional Product Use Issue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Folic Acid	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934507	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048091		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Xeljanz			S	Oral			Not Reported
	Tylenol			C	Unknown	650 Milligram, Bid		Not Reported
	Premarin			C	Unknown			Not Reported

Neurontin	C	Unknown	600 Milligram, Tid		Not Reported
Hydrodiuril	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Atacand	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17934587	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020IT173422		50 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestatic Liver Injury; Condition Aggravated; Hepatic Enzyme Increased; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lopinavir,Ritonavir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17935127	NON-EXPEDITED			US-PFIZER INC-2020243337		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17935737	DIRECT		DE, DS, HO, LT, RI, OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Cardiac Infection; Chest Discomfort; Coronary Artery Occlusion; Dyspnoea; Fall; Loss Of Consciousness; Nausea; Pulse Absent; Sars-Cov-2	Hydroxychloroquine 200mg			S		Quantity:1;	7 DAY	Not Reported

Test Negative

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936413	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1791107		43 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Cephalexin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Arava			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936441	EXPEDITED (15-DAY)		HO, OT	TN-PFIZER INC-2020238933			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia	Azithromycin			S		500 Mg, Daily (On Day 1)		Pfizer
	Azithromycin			S		250 Mg, Daily (From D2 To D5)		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day(For 10 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936473	EXPEDITED (15-DAY)		HO, OT	BR-IPCA LABORATORIES LIMITED-IPC-2020-BR-001991			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Azithromycin			C	Unknown	Unk		Not Reported

	Piperacillin-Tazobactam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936614	EXPEDITED (15-DAY)		OT	CA-ACCORD-185857			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown	Not Specified		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Not Specified		Not Reported
	Fosamax			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936619	EXPEDITED (15-DAY)		OT	CA-ACCORD-185895			Female	CAN

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

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S		1 Every 1 Days	Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S		2 Every 1 Days	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936637	EXPEDITED (15-DAY)		OT	CA-ACCORD-186362			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister;	Methotrexate			S	Unknown	Also Used For 11 Months		Accord

Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Arthrotec	S	Unknown	Not Reported
	Cimzia	S		Not Reported
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lipitor	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Dovobet	C	Topical	Not Reported
	Flovent	C	Respiratory (inhalation)	Not Reported
	Folic Acid	C	Oral	Not Reported
	Omeprazole	C	Oral	Not Reported
	Ventolin	C	Respiratory (inhalation)	Not Reported
	Vitamin D2	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624520		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Adalimumab	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17937048	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Retinopathy; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram, Qd		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Demerol			C	Unknown	Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			C	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

Prednisone	C	Unknown	1 Milligram, Qd		Not Reported
Prednisone	C	Unknown	2 Milligram, Qd		Not Reported
Prednisone	C	Unknown	3 Milligram, Qd		Not Reported
Prednisone	C	Unknown	4 Milligram, Qd		Not Reported
Prednisone	C	Unknown	5 Milligram, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17938147	EXPEDITED (15-DAY)		OT	CA-ACCORD-186307			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Accord
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown	Not Specified		Not Reported
	Celebrex			S	Oral	1 Every 1 Days		Not Reported
	Demerol			S	Unknown			Not Reported
	Erythromycin			S	Unknown	Not Specified		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S		Not Specified		Not Reported
	Lyrica			S	Unknown			Not Reported
	Pethidine			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Specified		Not Reported
	Erythromycin	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17938338	EXPEDITED (15-DAY)		HO	NVSC2020FR172857		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Rocephine			S	Oral	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17938558	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1058748		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haematology Test Abnormal; Hypokalaemia; Muscular Weakness; Nausea; Overdose; Somnolence; Suicide Attempt; Toxicity To Various Agents; Ventricular Tachycardia; Vomiting	Hydroxychloroquine			S	Oral	200 Milligram, 20 Tablets		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, 30 Tablets		Not Reported
	Prednisone			S	Oral	10 Milligram, 30 Tablets		Not Reported
	Diazepam			S	Intravenous bolus	Administered Over 30 Minutes, Approximately 4 Hours [5 Mg Iv Once At The Community Hospital]		Not Reported
	Diazepam			S	Intravenous bolus	80mg Iv Bolus Plus 39mg Iv From The Intermittent Boluses Every 2 Hours Tertiary Center		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17939407	EXPEDITED (15-DAY)		OT	NVSC2020ES174217		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Levofloxacin			S	Oral	500 Mg, Qd		Not Reported

	Hydroxychloroquine	S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine	S				Novartis
	Azitromicina	S	Oral	500 Mg, Qd		Not Reported
	Azitromicina	S				Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg, Once/Single (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17939434	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020241490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Off Label Use; Product Use Issue; Retinopathy; Treatment Failure	Methotrexate Sodium			S	Oral	15 Mg, Once Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Once Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Once Weekly		Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Myochrysine			S				Not Reported
	Orencia			S	Subcutaneous	125 Mg,Once Weekly		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Codeine			C				Not Reported
	Demerol			C				Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Once Weekly		Not Reported
	Humira			C	Subcutaneous	40 Mg, Once Every 2 Weeks		Not Reported
	Morphine			C				Not Reported
	Prednisone			C		2 Mg, 1x/Day		Not Reported
	Prednisone			C		3 Mg, 1x/Day		Not Reported
	Prednisone			C		4 Mg, 1x/Day		Not Reported
	Prednisone			C		1 Mg, 1x/Day		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 1 Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17939846	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020240683		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Mixed Liver Injury	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tacrolimus			S	Oral	8 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, 2x/Day (10 Mg/12 Hours)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940132	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1057534		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Off Label Use	Levofloxacin			S	Oral	500 Milligram, Qd		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Azitromicina			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Mylan
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Bid		Mylan
	Novorapid			C	Subcutaneous	10 International Unit, Q8h		Mylan
	Oseltamivir			C	Oral	75 Milligram, Q6h		Mylan
	Piperacilina + Tazobactam			C	Intravenous (not otherwise specified)	1 Dosage Form, Q8h		Mylan
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan
	Losartan			C	Oral	50 Milligram, Bid		Mylan
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940334	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047613			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940679	EXPEDITED (15-DAY)		DE	NVSC2020ES176296		84 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Novartis

	Azithromycin	C	Oral	Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940985	EXPEDITED (15-DAY)		DE, HO, OT	CA-APOTEX-2020AP012623		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bacteraemia; Body Temperature Increased; Central Nervous System Infection; Clostridium Difficile Infection; Confusional State; Decreased Appetite; Depressed Level Of Consciousness; Diarrhoea; Escherichia Infection; Headache; Nausea; Nervous System Disorder; Seizure; Somnolence; Stress Ulcer; Strongyloidiasis; Thrombosis; Upper Gastrointestinal Haemorrhage; Vomiting; Weight Decreased	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941659	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020ES129944		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Drug Ineffective; Product Use In Unapproved Indication; Pyrexia	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 5-10 Days)		Novartis
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17942304	EXPEDITED (15-DAY)		HO	NVSC2020IT173249		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S	Unknown	500 Mg, Qd (Off Label)		Novartis
	Plaquenil			S	Unknown	400 Mg, Qd (Off Label)		Not Reported
	Lasix			C	Unknown	25 Mg, Qd		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Normix			C	Unknown	Unk		Not Reported
	Dobetin			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Deltacortene			C	Unknown	Unk (Compresse)		Not Reported
	Pantorc			C	Unknown	20 Mg, Qd		Not Reported
	Cardirene			C	Unknown	75 Mg, Qd		Not Reported
	Metoprololo			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17942307	EXPEDITED (15-DAY)		HO	NVSC2020ES175531		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Paracetamol			S	Oral	1 G, Q8h (1gr Cada 8 Horas)		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Not Reported
	Hydroxychloroquine			S				Not Reported
	Cefditoren Pivoxil			S	Oral	400 Mg, Q12h (400 Mg Cada 12 Horas)		Not Reported
	Cefditoren Pivoxil			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	13284341	EXPEDITED (15-DAY)		OT	CA-SA-2017SA029762			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Oral	20 Mg,Qd		Not Reported
	Prednisone			S	Oral	50 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Oral	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Rituxan			S	Unknown	1 G, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported

	Tofacitinib Citrate		S	Unknown	5 Mg, Bid	Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	13669856	EXPEDITED (15-DAY)		OT	CA-SA-2017SA106082			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S				Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	14558242	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2262319-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Humira			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Infusion		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	14735736	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098039			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia;	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi

Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Plaquenil	S	Oral	Unk Unk,Unk	Sanofi
	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
	Celecoxib	S	Unknown	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Unknown	Unk Unk,Unk	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Align Digestive Aid	Not Reported
	Loperamide	C	Oral	2mg/1-2-Tabs 4x Per Day; Ongoing	Not Reported
	Loperamide	C	Oral	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk Unk,Tid	Not Reported
	Xeljanz	C	Oral	5 Mg,Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	14946375	NON-EXPEDITED			US-SA-2018SA142817			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	15333540	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019383		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	15342316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178182		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 1095.0 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Therapy Duration: 1095.0 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 274.0 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 274.0 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 61.0 Days		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 730.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 2920.0 Days		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 152.0 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 730.0 Days		Not Reported
	Arava			S	Oral	Therapy Duration: 30.0 Days		Not Reported

Arava	S	Unknown	Therapy Duration: 152.0 Days		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Arthrotec	C	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Imuran [Azathioprine]	C	Unknown			Not Reported
Prednisone	C				Not Reported
Azathioprine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	15419642	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086384			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate Sodium			S	Oral	35 Mg,Qw		Not Reported
	Risedronate Sodium			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Subcutaneous	17.5 Mg,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	300 Mg, Qcy		Sanofi
	Sodium Aurothiomalate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Sanofi
	Plaquenil			S	Oral	300 Mg,Qd		Sanofi
	Plaquenil			S	Oral	300 Mg, Qd		Sanofi
	Arava			S	Oral			Sanofi
	Actonel			S		35 Mg, Qw		Not Reported
	Leflunomide			S	Oral	20 Mg, Qcy		Sanofi
	Leflunomide			S	Oral	20 Mg, Qh		Sanofi

Risedronic Acid	S		35 Mg, Qw	Not Reported
Anakinra	S	Subcutaneous	100 Mg	Not Reported
Anakinra	S	Subcutaneous	100 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	35 Mg, Qw	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported
Actemra	S	Unknown	Unk Unk,Unk	Not Reported
Actemra	S	Subcutaneous	Unk Unk,Unk	Not Reported
Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G,Qcy	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S			Not Reported
Xeljanz	S	Oral	10 Mg, Qd	Not Reported
Xeljanz	C			Not Reported
Risedronate	C			Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	15621214	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557049-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Operation;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Coversyl	C	Oral	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Leucovorin Calcium	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Leucovorin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	15629606	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555539-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Cough; Diarrhoea; Diarrhoea; Drug Ineffective; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported
	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	15849613	EXPEDITED (15-DAY)		OT	CA-SA-2019SA012286			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16293525	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121694			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Unk		Sanofi
	Plaquenil			S	Oral	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16648254	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202788			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		100 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Apo-Azathioprine			S	Unknown	100 Mg		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Apo-Minocycline			S	Unknown	50 Mg		Not Reported
	Minocycline			S	Unknown			Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	S	Unknown	5.0 Mg, Bid		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Mg		Not Reported
Amoxicillin And Clavunate Potassium	C	Unknown			Not Reported
Amoxil [Amoxicillin]	C	Unknown			Not Reported
Bcg	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16651233	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203472			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		5 Mg, Qd. 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16651244	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203475			Unknown	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Plaquenil	S			Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	S			Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16666982	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210837			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16672660	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA211386			Unknown	CAN

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

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine		S	Unknown	200 Mg	Sanofi
	Leflunomide		S	Unknown	10 Mg, 1 Every 1 (Days)	Sanofi
	Methotrexate		S	Unknown	15 Mg	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported
	Arava		C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Oral	200 Mg, 2 Every 1 (Days)	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Simponi		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16691240	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208331			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	16732748	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Meloxicam			S	Oral	7.5 Milligram, Once A Day		Aurobindo
	Pantoprazole			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Cosentyx			S	Oral	300 Milligram, 1 Every 1 Month(S)		Not Reported
	Diclofenac			S	Oral	Unk, 3 Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Leucovorin Calcium			S	Oral	5 Milligram, Every Week		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Methotrexate			S	Oral	4 Dosage Form, Every Week		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Diltiazem Hydrochloride			C	Oral	240 Milligram		Not Reported
	Fluticasone Propionate			C		Unk		Not Reported
	Mar-Pantoprazole			C	Unknown	Unk		Not Reported
	Mometasone Furoate			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Salbutamol Sulfate			C		Unk		Not Reported
	Tramadol Hydrochloride			C	Oral	Unk, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17255276	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17560623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567748		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17579774	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327867		63 YR	Female	CAN

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

Adverse Event; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17679788	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097024			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Cefazolin			S		Unk		Not Reported
	Leflunomide			S	Oral	10.0 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25.0 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported
	Cimzia			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Rituximab			S		Unk		Not Reported

	Enbrel	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
	Arava	C		Unk	Not Reported
	Viread	C		Unk	Not Reported
	Naproxen	C		2 Df, Qd (Dose: 500 Mg)	Not Reported
	Xeljanz	C	Oral	2 Df, Qd (Dose: 5.0 Mg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17682579	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202003002825			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arrhythmia; Lung Assist Device Therapy; Off Label Use; Pneumonia; Pulmonary Embolism; Respiratory Failure	Hydroxychloroquine			S		600 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Amikacin			S	Intravenous (not otherwise specified)	2200 Mg, Qd		Not Reported
	Furosemide			C		Unk		Not Reported
	Retinol			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Morphine			C		Unk Mg		Not Reported
	Macrogol			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17683880	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA101018			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported
	Prednisone			C	Unknown			Not Reported
	Aleve			C	Unknown	Unk, Prn		Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17688919	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100879			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Azathioprine			S				Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Q6w	Not Reported
	Pariet	C		20 Mg, Qd	Not Reported
	Folic Acid	C		5 Mg, Qd; 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17716273	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0122393			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Atorvastatin			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Asa Ec			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17743411	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17769784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592615		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Calcium	C			Not Reported
	Magnesium	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17805206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598696		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17814994	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832711		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz Xr	C	Unknown		Not Reported
Actemra	C	Intravenous (not otherwise specified)		Not Reported
Simponi	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17817630	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006337			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Oral	400 Mg, Freq: Unk X 1 Days		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Apo Lefunomide			S	Unknown	20 Mg, Freq: Unk X 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17856413	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535375		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cephalexin /00145501/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17861413	EXPEDITED (15-DAY)		HO, OT	IT-SA-2020SA138478			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis	Plaquenil			S	Oral			Sanofi
	Plaquenil			S				Sanofi

Bullous; Face Oedema; Localised Oedema; Off Label Use; Skin Exfoliation	Darunavir	S	Oral		Not Reported
	Piperacillin Sodium/Tazobactam Sodium	S		4g/0.5 G	Not Reported
	Clexane	S	Subcutaneous		Sanofi
	Ritonavir Sandoz	S	Oral		Not Reported
	Insulin	C			Not Reported
	Depakin Chrono [Valproate Sodium]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17875841	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609634			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17875843	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated;	Remicade			S	Intravenous (not			Janssen

Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting			otherwise specified)		
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17878927	EXPEDITED (15-DAY)		LT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001755			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypotension; Palpitations; Tachycardia	Hydroxychloroquine Sulfate			S	Oral	200 Milligram		Ipca
	Doxazosin			C	Unknown	Unk		Not Reported
	Verapamil Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17880956	EXPEDITED (15-DAY)		LT	FR-ROCHE-2616499		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Multiple Organ Dysfunction Syndrome; Septic Shock	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Roactemra	S	Intravenous (not otherwise specified)	Not Reported
	Clairyg	C	Unknown	Not Reported
	Midazolam Mylan	C	Unknown	Not Reported
	Cisatracurium	C	Intravenous (not otherwise specified)	Not Reported
	Sufentanil	C	Intravenous (not otherwise specified)	Not Reported
	Noradrenaline [Norepinephrine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17938415	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Sulfasalazine			C	Unknown	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17938606	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-030317			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

Prednisone	S	Unknown	2 Milligram, Once A Day		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17938645	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-028435		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Amlodipine			S	Oral	10 Milligram, Once A Day		Aurobindo
	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin Film-Coated Tablets			S	Oral	250 Milligram, Once A Day		Aurobindo
	Enoxaparin Sodium			S	Intramuscular	4000 International Unit, Once A Day		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram, 3 Times A Day		Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported
	Enoxaparin			C	Intramuscular	4000 International Unit, Once A Day		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported
	Spironolactone			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Esidrex			C	Unknown	Unk		Not Reported
	Tanganil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17938749	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201905-001410			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Condition Aggravated; Steroid Diabetes	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet,		Concordia
	Prednisolone			S	Oral	50 Mg		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	35 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	11 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Losartan Potassium			C		Unk		Not Reported
	Persantin-L			C		Unk		Not Reported
	Ursodeoxycholic Acid			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Omeprazole			C				Not Reported
	Alfacalcidol			C		Unk		Not Reported
	Zetia			C		Unk		Not Reported
	Bezafibrate			C		Unk		Not Reported
	Azosemide			C		Unk		Not Reported
	Spironolactone			C		Unk		Not Reported
	Cellcept			C		Unk		Not Reported
	Actonel			C		Unk		Not Reported

	Tocopherol	C	Unk		Not Reported
	Daiphen	C	Unk		Not Reported
	Daiphen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17938818	EXPEDITED (15-DAY)		OT	CA-ROCHE-2625997		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Intentional Product Use Issue; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mesalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Oral			Not Reported

	Diphenhydramine	C	Oral	Not Reported
	Atacand Plus	C	Oral	Not Reported
	Bisoprolol Fumarate	C	Oral	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Ebastine	C		Not Reported
	Ferrous Gluconate	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17938946	EXPEDITED (15-DAY)		HO	CA-ROCHE-2626175			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoaesthesia; Infection; Nausea; Nephrolithiasis; Nerve Injury; Neutropenia; Off Label Use; Osteoarthritis; Pain In Extremity; Paraesthesia; Product Use Issue; Pulmonary Congestion; Synovitis; White Blood Cell Count Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn E			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17939164	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02969		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Metronidazole			S	Unknown	Unk		Lupin
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Milligram, Single		Not Reported
	Tocilizumab			C				Not Reported
	Cefepime			C	Unknown	Unk		Not Reported
	Midazolam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Propofol			C	Unknown	Unk		Not Reported
	Dexmedetomidine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17939198	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02970		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Midazolam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Propofol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17939809	EXPEDITED (15-DAY)		DE, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251378		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Lopinavir+Ritonavir			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	800 Milligram, Daily		Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	1 Gram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17941861	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-030273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	20 Milligram, Once A Day		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942528	EXPEDITED (15-DAY)		OT	IR-APPCO PHARMA LLC-2086664		70 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Retinal Haemorrhage; Retinal Vein Occlusion; Withdrawal Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942532	NON-EXPEDITED			US-ADVANZ PHARMA-202006006596			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Wrong Technique In Product Usage Process	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		One And A Half Once A Day, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942686	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02963		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Heparin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942687	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02960		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

	Enoxaparin		C	Subcutaneous	1 Milligram/Kilogram, Bid	Not Reported
	Tissue Plasminogen Activator, Recombinative		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942756	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1791027		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination	Hidroxicloroquina (2143a)			S	Oral			Teva
	Azitromicina (7019a)			S	Oral			Not Reported
	Interferon Beta-1b (2305od)			S		250 Mg		Not Reported
	Enoxaparina (2482a)			C				Not Reported
	Kaletra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942761	EXPEDITED (15-DAY)		OT	NVSC2020FR173265			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Novartis
	Azithromycin			S				Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942777	EXPEDITED (15-DAY)		OT	NVSC2020IT150106		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Clexane			S	Subcutaneous	4 Kiu, Qd		Not Reported
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942842	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202006006685			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Covid-19; Diarrhoea; Hypophagia; Myalgia; Nausea; Pyrexia; Tachycardia; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Prednisone			S	Unknown	Unk (High-Dose)		Not Reported
	Prednisone			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942924	EXPEDITED (15-DAY)		HO	NVSC2020FR175361		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942938	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624285		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Rabeprazole Sodium	C	Oral		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942993	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048332		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Therapeutic Product Effect Decreased; Ulcer	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Celebrex			S	Unknown	200 Milligram, Bid		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Qd		Not Reported
	Betaloc [Metoprolol Tartrate]			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Losec [Omeprazole]			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943016	EXPEDITED (15-DAY)		HO, OT	BR-APPCO PHARMA LLC-2086669		29 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Off Label Use; Transaminases Increased	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Azithromycin			C	Unknown			Not Reported
	Piperacillin-Tazobactam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943107	EXPEDITED (15-DAY)		OT	IR-APPCO PHARMA LLC-2086672		45 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Retinal Haemorrhage; Withdrawal Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943158	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048404		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943196	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201801-000115			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Contusion; Disability; Drug Ineffective; Fatigue; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling; Swelling	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	20 Mg, Unk, 2 Years		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943204	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048590		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Alendronic Acid			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Myochrysine			S	Parenteral	50 Milligram, Qmo		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
	Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	10 Milligram, Q2h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943277	EXPEDITED (15-DAY)		DE, OT	IT-DRREDDYS-GER/ITL/20/0124387		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukocytosis; Pyrexia; Respiratory Distress; Sepsis	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported
	Clopidogrel			S	Oral	300 Mg		Not Reported
	Tirofiban			S	Intravenous bolus	25 Migrogram/Kgbody		Not Reported
	Tirofiban			S	Intravenous (not otherwise specified)	0.15 Microgram/Kgbody Per Minute For 48 Hours		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	2.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Methylprednisolone			S	Unknown	1 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943424	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047969		62 YR	Male	CAN

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

Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943583	EXPEDITED (15-DAY)		HO	CA-ROCHE-2625487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Heart Rate Increased; Herpes Zoster;	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Tazobact [Piperacillin Sodium\Tazobactam Sodium]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amiodarone Hydrochloride			C	Unknown			Not Reported
	Apo-Ketorolac			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported

Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Escitalopram	C	Unknown	Not Reported
	Humalog	C	Intravenous (not otherwise specified)	Not Reported
	Hydrochlorothiazid	C	Unknown	Not Reported
	Januvia [Sitagliptin]	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Slow-K	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Ventolin [Salbutamol]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943613	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported

Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943656	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048377		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Diverticulitis; Drug Hypersensitivity; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Oxycodone Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Ilaris			C	Subcutaneous			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943667	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1058722		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy; Premature Separation Of Placenta	Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943728	EXPEDITED (15-DAY)		HO	BE-AMNEAL PHARMACEUTICALS-2020-AMRX-01795		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemolysis; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Bid (Day 1)		Amneal
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid (Day 2-5)		Amneal
	Azithromycin			C	Unknown	500 Milligram (Day 1)		Not Reported
	Azithromycin			C	Unknown	250 Milligram (Day 2-5)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943749	EXPEDITED (15-DAY)		CA	FR-MYLANLABS-2020M1058769			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Leflunomide			S	Transplacental	Unk		Not Reported
	Methotrexate			S	Transplacental	Unk		Not Reported
	Deflazacort			S	Transplacental			Mylan
	Chloroquine			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan
	Hydrochlorothiazide			S	Transplacental	Unk		Mylan
	Indometacin			S	Transplacental	Unk		Mylan
	Methyldopa			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943837	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2712676-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Furuncle; Pain; Pulmonary Fibrosis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943846	EXPEDITED (15-DAY)		HO	NVSC2020ES179128		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina			S	Oral	500 Mg, Qd		Novartis
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported
	Roactemra			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	2u Cada 12h		Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Hidroxicloroquina			S	Oral	400 Mg, Q24h		Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943857	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1057706		58 YR	Male	ESP

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

Diarrhoea; Hallucination; Off Label Use	Azithromycin	S	Oral	Unk	Not Reported
	Hidroxicloroquina /00072601/	S	Oral	Unk	Mylan
	Interferon Beta-1b	S		250 Milligram, Q2d	Mylan
	Enoxaparina	C		Unk	Mylan
	Kaletra	C		Unk	Mylan
	Genvoya	C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944138	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020107055			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Oral	1 Df, Qd		Glaxosmithkline
	Leucovorin Calcium			S	Oral	5 Mg, Qw		Glaxosmithkline
	Cosentyx			S	Oral	300 Mg, Qmo		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Mg, Qd		Not Reported
	Diltiazem Hydrochloride			C	Oral	240 Mg, Unknown		Glaxosmithkline
	Fluticasone Propionate			C	Respiratory (inhalation)	Unk		Glaxosmithkline
	Salbutamol			C	Unknown	Unk		Glaxosmithkline

Premarin	C	Unknown	Unk		Not Reported
Pantoprazole Sodium Sesquihydrate	C	Unknown	Unk		Not Reported
Mometasone Furoate	C	Unknown	Unk		Not Reported
Tramadol Hydrochloride	C	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944149	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Joint Swelling; Product Use Issue; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944174	EXPEDITED (15-DAY)		HO	NVSC2020ES173961		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Once/Single (600 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944191	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1792687		83 YR	Female	CAN

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

Drug Ineffective; Pulmonary Fibrosis	Minocycline	S	Unknown	200 Milligram Daily;		Actavis
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944464	EXPEDITED (15-DAY)		OT	CA-ROCHE-2628638		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944486	EXPEDITED (15-DAY)		OT	CA-ROCHE-2629128			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944521	EXPEDITED (15-DAY)		OT	CA-ROCHE-2629073		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17944545	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1058496		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid On Day 1		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17945405	EXPEDITED (15-DAY)		OT	NVSC2020ES173558		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg, Qd, Dia		Novartis
	Azithromycin			S				Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (Dia)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Tocilizumab			S	Intravenous (not	600 Mg, Once/Single		Not Reported

					otherwise specified)					
	Tocilizumab			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17945414	EXPEDITED (15-DAY)		DE	NVSC2020ES176754		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Dexketoprofen "Sandoz"			S	Intravenous (not otherwise specified)	25 Mg, Q8h		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Once/Single		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17945903	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048573		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk		Not Reported
	Cetrizine	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
	Naproxen Sodium	C	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946154	EXPEDITED (15-DAY)		OT	NVSC2020ES173561		43 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (Dia)		Novartis
	Hydroxychloroquine Sulfate			S				Novartis
	Paracetamol			S	Oral	1 G, Q8h (1gr Cada 8 Horas)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048793		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram/ 2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk/ Solution		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not	300 Milligram, Q6wk/		Not Reported

				otherwise specified)	Powder For Solution		
	Rituximab		S	Intravenous drip	Unk		Not Reported
	Sulfasalazine		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946360	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946379	EXPEDITED (15-DAY)		HO	NVSC2020ES179131		9 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina			S	Oral	360 Mg, Qd (360 Mg Dia)		Not Reported
	Azitromicina			S				Not Reported
	Hydroxychloroquine			S	Oral	120 Mg, Q12h (120 Mg		Novartis

Cada 12h)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946511	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020243379			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, 1x/Day		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	200 Mg, 1x/Day		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947055	EXPEDITED (15-DAY)		LT	NVSC2020US178710			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Heart Rate Increased	Methotrexate			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17949372	EXPEDITED (15-DAY)		HO	NVSC2020ES176256		60 YR	Male	ESP

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

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Mg, Qd	Novartis
	Azithromycin	S			Novartis
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, Once/Single	Not Reported
	Tocilizumab	S			Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17949470	EXPEDITED (15-DAY)		OT	NVSC2020ES177480		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis
	Sulpirida			S	Oral	50 Mg, Q8h		Not Reported
	Enoxaparina			S	Subcutaneous	40 Mg, Q24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17949473	EXPEDITED (15-DAY)		HO	NVSC2020ES176626		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Linezolid			S	Intravenous (not otherwise specified)	600 Mg, Q12h		Novartis
	Meropenem			S	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported
	Roactemra			S	Unknown	600 Mg, Once/Single		Not Reported
	Roactemra			S				Not Reported
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)	1 Df, Q8h		Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 G, Q8h		Not Reported
	Hidroxicloroquina			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17949536	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3460183-00		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Lopinavir/Ritonavir			S	Oral	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido		Not Reported
	Metilprednisolona			S	Unknown	Día 1: Bolo De 80mg, Del 08/04 Al 16/04 En Pauta Descendente		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2.000 Mg Inyectable Iv		Not Reported
	Dolquine			S	Oral	Dolquine 200 Mg Comprimidos Recubiertos		Not Reported
	Azitromicina			S	Unknown			Not Reported
	Metamizol			C	Unknown	Metamizol 2.000 Mg Inyectable 5 Ml		Not Reported
	Clexane			C		Clexane 4.000 Ui (40 Mg)/ 0,4 Ml Solucion Inyectable En Jeringa Precargada		Not Reported
	Omeprazol			C		Omeprazol 20 Mg Cápsula		Not Reported
	Metoclopramida			C		Metoclopramida 10 Mg Inyectable 2 Ml		Not Reported
	Paracetamol			C		Paracetamol 1.000 Mg Inyectable Perfusión 100 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17949677	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Pneumonia; Rheumatoid Arthritis	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17949858	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-20785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	12393139	NON-EXPEDITED			US-PFIZER INC-2016261510		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Celebrex			S		200 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		8 Pill Once On Wednesday		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Prednisone			C		5 Mg, As Needed		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	13233820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893888		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation; Treatment Failure; Vein Disorder	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration :2190.0 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Fosavance			C				Not Reported
	Synthroid			C	Unknown			Not Reported

Alendronate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	14633591	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Musculoskeletal Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	14921644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044730		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	20 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown		Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	200 Milligram, Bid	Not Reported
	Prednisone	C	Unknown	7.5 Milligram, Qd	Not Reported
	Tridural	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Cimetidine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	15977906	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013546			Female	CAN

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

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	16081413	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013665		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Incorrect Route Of Product Administration; Infection; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Occlusive Dressing Technique		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Every 3 Weeks		Not Reported
	Myochrysine			S	Intramuscular	60 Milligram, Every 3 Weeks		Not Reported
	Nortriptyline Hydrochloride			S	Oral	10 Milligram		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Two Times A Day		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every One Month		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Every 3 Weeks		Not Reported
	Orencia			S	Vaginal	750 Milligram, Every 1 Month		Not Reported
	Orencia			S	Intravenous (not	750 Milligram, Every 4		Not Reported

		otherwise specified)	Weeks	
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Sulfasalazine	S	Oral	2.5 Milligram, Once A Day	Not Reported
Sulfasalazine	S	Oral	2.5 Gram, Once A Day	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Vitamin B1	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
Omega-3	S	Unknown	Unk	Not Reported
Omega-3	S	Unknown	1200 Milligram, Two Times A Day	Not Reported
Fentanyl Matrix	S	Unknown	Unk	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	1 Dosage Form	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	70 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750.0 Milligram, 1 Every 4 Weeks	Not Reported
Actonel	C	Unknown	36 Milligram, Every Week	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Once A Day	Not Reported
Ergocalciferol	C	Unknown	400 International Unit,	Not Reported

			Once A Day	
Ergocalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	400 International Unit, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	400 Milligram, Two Times A Day	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Once A Day	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Two Times A Day	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	5 Gigabecquerel, Once A Day	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Once A Day	Not Reported
Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
Tylenol	C	Unknown	100 Milligram, Once A Day	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Percocet	C	Unknown	Unk	Not Reported
Vitamin D 3	C	Unknown	Unk	Not Reported
Lomotil	C	Unknown	Unk	Not Reported
Oxycocet	C	Unknown	Unk	Not Reported
Vitamin C	C	Unknown	Unk	Not Reported

Biotin	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Vitamin B6	C	Unknown	Unk	Not Reported
Vitamin E	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	1 Dosage Form	Not Reported
Calcium	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200.0 Milligram, Two Times A Day	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram, Once A Day	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Every Week	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	16341521	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028115		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib			S	Oral	Unk		Aurobindo
	Gabapentin			S	Oral	100 Milligram, Two Times A Day (2 Every 1 Day)		Aurobindo
	Gabapentin			S	Oral	100 Milligram, Once Every Two Weeks		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Oral	Unk		Not Reported
	Celebrex			S	Oral	Unk, Once A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Week		Not Reported
	Myochrysine			S	Intramuscular	60 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Week		Not Reported
	Orencia			S	Vaginal	750 Milligram, 1 Evry 1 Month		Not Reported
	Orencia			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported

Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Sulfasalazine	S	Oral	2.5 Gram, Once A Day	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Once A Day	Not Reported
Nortriptyline Hydrochloride	S	Oral	10 Milligram, 1 Every 1 Hour	Not Reported
Nortriptyline Hydrochloride	S	Oral	10 Milligram	Not Reported
Methotrexate	S	Unknown	Unk, Once A Week	Not Reported
Apo-Gabapentin	S	Oral	100 Milligram, Two Times A Day	Not Reported
Arava	S	Oral	20 Milligram, Once A Day	Not Reported
Lomotil	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Lomotil	C	Unknown	Unk	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
Nasonex	C	Unknown	Unk	Not Reported
Nexium	C	Unknown	40.0 Milligram, Two Times A Day	Not Reported
Nortriptyline	C	Oral	10 Gigabecquerel, 1 Every 1 Hour	Not Reported
Omega 3	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Omega 3	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Percocet	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Trazodone	C	Oral	50 Milligram, 1 Every 1 Hour	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Vitamin D	C	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	36 Milligram, Once A Day	Not Reported
Calcium	C	Unknown	Unk Unk, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk, 1 Every 1 Hour	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Once A Day	Not Reported
Fergon	C	Unknown	300 Milligram, Once A Day	Not Reported
Genteal	C	Unknown	Unk	Not Reported
Aclasta	C	Unknown	750 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram	Not Reported
D-Alpha Tocopherol	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	Unk Unk, Once A Day	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported

Pantoprazole Magnesium	C	Unknown	400 Milligram, Once A Day	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Salmo Salar Oil	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Two Times A Day	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Once A Day	Not Reported
Fish Oil	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hcl	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Once A Day	Not Reported
Zoledronic Acid	C	Unknown	Unk	Not Reported
Fentanyl	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	16346219	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-028343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Rosuvastatin Tablet			S	Unknown	Unk		Aurobindo
	Vancomycin Hydrochloride			S	Unknown	Unk		Aurobindo
	Ceftazidime			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	500 Milligram, Two Times A Day		Not Reported
	Cellcept			S	Unknown	500 Milligram, Two Times A Day		Not Reported
	Cellcept			S	Unknown	2 Dosage Form, Once A Day		Not Reported
	Lasix			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Plaquenil			S	Unknown	2 Dosage Form, Once A Day		Not Reported
	Prednisone			S	Unknown	10 Milligram, Daily		Not Reported
	Prednisone			S	Unknown	7.5 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported

Actonel	C	Unknown	Unk	Not Reported
Apo Amlo	C	Unknown	Unk	Not Reported
Apo K	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Oral	50 Milligram	Not Reported
Epoetin Alfa	C	Unknown	Unk	Not Reported
Escitalopram	C	Unknown	10 Milligram	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Insulin Lispro	C	Unknown	Unk Unk, 3 Times A Day	Not Reported
Januvia	C	Unknown	Unk	Not Reported
Kcl	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Metoprolol	C	Unknown	Unk	Not Reported
Pantoloc	C	Unknown	40 Milligram, Daily	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Risedronate	C	Unknown	35 Milligram, Every Week	Not Reported
Slow K	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Ventolin	C	Unknown	Unk	Not Reported
Eprex	C	Intravenous (not otherwise specified)	Unk	Not Reported
Amiodarone Hydrochloride	C	Unknown	Unk	Not Reported
Piperacillin;Tazobactam	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17002748	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-120021			Female	CAN

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

Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia		S	Subcutaneous	125 Milligram, Qwk	Bristol Myers Squibb
	Enbrel		S	Unknown	50 Milligram, Qwk	Not Reported
	Actemra		S	Subcutaneous	162 Milligram	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Oral	10 Milligram, Qwk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17015903	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457996		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Winpred	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17389402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536025		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17405411	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008376		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17791596	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050851			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Single		Not Reported
	Kaletra			S	Oral	2u Cada 12h		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Not Reported
	Dolquine			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17798522	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2020M1047718		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Trazodone			S		1 Dosage Form, Qd 1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The Evening		Not Reported
	Trazodone			S		Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Day 1: 400mg 2x/D Day 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg 08/04 To 10/04		Mylan
	Zyprexa			S		Unk		Mylan
	Zyprexa			S		1/2 Tablet 2x/Day Treatment Was Suspended For 2 Days 11/04 And 12/04 And Then Resumed		Mylan
	Algostase Mono			S		1 Df, Tid		Mylan
	Contramal			S		1 Dosage Form, Prn		Mylan
	Pradaxa			S		Unk		Mylan
	Movicol /01749801/			S		1 Df, Qd		Mylan
	Uni Diamicron			S		60 Mg, Bid		Mylan
	L-Thyroxine /00068001/			S		150 Microgram, Qd		Mylan
	Metformin			S		500 Mg, Bid		Mylan
	Magnetop /00434501/			S	Oral	450 Mg, Qd		Mylan
	Clexane			S		Unk		Mylan
	Perindopril			S		2 Mg, Qd		Mylan
	Kalium /00031401/			S	Oral	600 Mg		Mylan
	Prolopa			S		0.5 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17799620	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1048589		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid, 2u Cada 12h		Mylan
	Kaletra			S				Mylan
	Dolquine			S	Oral	400 Milligram, Qd, 400 Mg Dia		Mylan
	Dolquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17807933	EXPEDITED (15-DAY)		LT	NVSC2020ES129940		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 5-10 Days)		Novartis
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported
	Everolimus			C	Unknown	Unk		Not Reported
	Everolimus			C				Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17823135	EXPEDITED (15-DAY)		OT	NVSC2020US142630			Unknown	USA

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

Foetal Exposure During Pregnancy; Premature Baby	Methylprednisolone	S	Transplacental	Unk (Mother Dose 1 G And 1 Mg/Kg)	Novartis
	Amoxicillin	S	Transplacental	Unk (Mother Dose: 500 Mg Daily)	Not Reported
	Azithromycin	S	Transplacental	Unk (Mother Dose: 500 Mg Daily)	Not Reported
	Vancomycin	S	Transplacental	Unk (Mother Dose: 750 Mg, Q8h And 1250 Mg, Q8h)	Not Reported
	Fluconazole	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	Unk (Mother Dose: 200 Mg Bid)	Not Reported
	Prednisone	S	Transplacental	Unk (Mother Doses: 70 Mg Qd, 60 Mg Qd, 50 Mg Qd, 40 Mg Qd)	Not Reported
	Cefepime	S	Transplacental	Unk (Mother Dose: 2g Q8h)	Not Reported
	Acyclovir	S	Transplacental	Unk (Mother Dose: 800 Mg Qd)	Not Reported
	Acyclovir	S	Transplacental	Unk (Mother Dose: 5 Mg/Kg, Q8h)	Not Reported
	Cyclophosphamide	S	Transplacental	Unk (Mother Dose: 500 Mg And 840 Mg)	Not Reported
	Magnesium Sulfate	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17827283	EXPEDITED (15-DAY)		HO, OT	RU-SA-2020SA135428			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Iron Deficiency Anaemia; Placental Disorder; Placental Insufficiency; Pre-Eclampsia	Clexane			S	Subcutaneous	0.4 Unk, Qd		Sanofi
	Clexane			S	Subcutaneous	0.4 Unk, Bid		Sanofi
	Clexane			S	Subcutaneous	0.4 Unk, Bid		Sanofi
	Prednisolone			S	Oral	4 Tab-Morning,3 Tab-		Not Reported

			Noon,1tab-Evening	
Methylprednisolone	S	Oral	8 Df, Qd	Not Reported
Nifedipine	S		30 Mg, Bid	Not Reported
Nifedipine	S		30 Mg, Qd	Not Reported
Nifedipine	S		30 Mg, Qd	Not Reported
Nifedipine	S		60 Mg-Morning,30 Mg-Evening Bid	Not Reported
Methyldopa	S	Oral	0.5 Df, Qd	Not Reported
Methyldopa	S	Oral	0.5 Df, Tid	Not Reported
Methyldopa	S		1.5 Df, Qid	Not Reported
Methyldopa	S		1.5 Df, Qid	Not Reported
Omeprazole	S	Oral	1 Df, Bid	Not Reported
Levothyroxine Sodium	S		Unk	Not Reported
Progesterone	S		400mg Qd From 14 Weeks	Not Reported
Fosfomycin	S		3 G, Hs	Not Reported
Fosfomycin	S		3g Qw On Friday	Not Reported
Dipyridamole	S		75 Mg, Bid	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Oral	1 Df, Tid	Not Reported
Plaquenil	S	Oral	1 Df Bid, 1 Tab-Noon, 1 Tab-Evening	Sanofi
Folic Acid	S	Oral	1 Df, Tid	Not Reported
Cefepime Hydrochloride	S	Intravenous (not otherwise specified)	Unk	Not Reported
Magnesium Sulfate	S	Intravenous drip	Unk	Not Reported
Methylprednisolone	S	Intravenous drip	250 Nacl Sol 0.9%, 100 1 Iv Drip-30 Min, Twice A Week	Not Reported
Methylprednisolone	S	Intravenous drip	500+ Nacl Sol. 0.9%,100 Iv Drip-30 Min, Twice In Week	Not Reported

	Ceftaroline Fosamil	S	Intravenous drip	600mg In Nacl Solution 0.9% -100 Iv Drip- 1 Hour	Not Reported
	Azathioprine	S		50 Mg, Qd, In Morning	Not Reported
	Azathioprine	S		50 Mg, Bid	Not Reported
	Suprastin	S	Oral	1 Df, Hs	Not Reported
	Suprastin	S	Oral	1 Df, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17868155	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2607024		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache;	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Cyclosporine			S	Unknown			Not Reported
	Apo-Cyclosporine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Codeine	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cyclosporin	S	Oral	Not Reported
	Abatacept	S	Unknown	Not Reported
	Abatacept	S		Not Reported
	Etanercept	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Etanercept	S		Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Ustekinumab	S	Oral	Not Reported
	Ustekinumab	S	Subcutaneous	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfamethoxazole	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Otezla	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Otezla	S		Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Unknown	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Ibuprofen	S	Oral		Not Reported
Ibuprofen	S	Oral		Not Reported
Ibuprofen	S	Oral		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Simponi	S	Subcutaneous		Not Reported
Acide Folique	C			Not Reported
Actonel	C			Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C			Not Reported
Cannabis Sativa	C			Not Reported
Colchicine	C	Oral		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown	Prolonged-Release Capsule	Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C			Not Reported
Gravol	C			Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Mogadon	C	Unknown		Not Reported

Naproxen	C	Unknown			Not Reported
Nitrazepam	C	Oral			Not Reported
Nitrazepam	C	Unknown			Not Reported
Oxycodone	C	Unknown			Not Reported
Oxycodone	C	Unknown			Not Reported
Oxycodone Hydrochloride	C	Unknown			Not Reported
Oxycodone Hydrochloride	C	Unknown			Not Reported
Oxyneo	C	Unknown			Not Reported
Prednisone	C				Not Reported
Risedronate Sodium	C	Oral			Not Reported
Uloric	C	Oral			Not Reported
Uloric	C	Unknown			Not Reported
Uloric	C	Oral			Not Reported
Uloric	C	Oral			Not Reported
Vitamin D3	C	Oral	2000 Iu		Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17907316	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1055873		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Levofloxacin			S	Oral	1 Dosage Form, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17913702	EXPEDITED (15-DAY)		LT, OT	NVSC2020FR168884		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein	Hydroxychloroquine Sulfate			S	Other	600 Mg, Qd		Novartis

Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Overdose; Oxygen Saturation Decreased; Pneumonia Bacterial; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate	S	Other	1000 Qd	Novartis
	Hydroxychloroquine Sulfate	S	Other	400 Mg, Qd	Novartis
	Paracetamol	S	Other	4 G, Qd	Not Reported
	Paracetamol	S			Not Reported
	Lovenox	S	Subcutaneous	0.6 Ml, Qd	Not Reported
	Lovenox	S	Subcutaneous	0.7 Ml, Qd	Not Reported
	Lovenox	S	Subcutaneous	1.4 Ml, Qd	Not Reported
	Movicol	C	Other	2 Df, Qd	Not Reported
	Movicol	C			Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	20 Mg, Qd	Not Reported
	Pantoprazole	C	Oral	40 Mg, Qd	Not Reported
	Pantoprazole	C			Not Reported
	Pantoprazole	C			Not Reported
	Pantoprazole	C			Not Reported
	Lantus	C	Subcutaneous	20 Iu, Qd	Not Reported
	Tienam	C	Intravenous (not otherwise specified)	1 G, Q8h	Not Reported
	Lasilix	C	Parenteral	40 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17920002	EXPEDITED (15-DAY)		DE, OT	IT-AUROBINDO-AUR-APL-2020-029742		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukocytosis; Pyrexia; Respiratory Distress; Sepsis	Clopidogrel			S	Oral	75 Milligram, Once A Day		Aurobindo
	Clopidogrel			S	Oral	300 Milligram		Aurobindo
	Acetylsalicylic Acid			S	Intravenous (not otherwise specified)	250 Milligram		Not Reported
	Acetylsalicylic Acid			S	Oral	75 Milligram, Once A Day		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	2.5 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Methylprednisolone	S	Unknown	1 Milligram/Kilogram	Not Reported
	Tirofiban	S	Intravenous (not otherwise specified)	0.15 Milligram/Kilogram, Body Per Minute For 48 Hours	Not Reported
	Tirofiban	S	Intravenous bolus	25 Milligram/Kilogram, Body	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17929322	EXPEDITED (15-DAY)		HO, LT	NVSC2020ES173471		26 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Suicide Attempt	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine			S				Novartis
	Allopurinol			C	Oral	100 Mg, Qd		Not Reported
	Paracetamol			C	Oral	1 G, Q8h		Not Reported
	Famotidine			C	Oral	20 Mg, Qd		Not Reported
	Doxazosina			C	Oral	4 Mg, Qd		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Cefixima			C	Oral	200 Mg, Q12h		Not Reported
	Prednisona			C	Unknown	5 Mg, Qd		Not Reported
	Prednisona			C	Oral	20 Mg, Qd		Not Reported
	Prednisona			C	Oral	20 Mg, Qd		Not Reported
	Carvedilol			C	Oral	25 Mg, Q12h		Not Reported
	Zemplar			C	Oral	1 Ug, Qd		Not Reported
	Myfortic			C	Oral	360 Mg, Q12h		Not Reported
	Enoxaparina			C	Subcutaneous	20 Mg, Qd		Not Reported
	Fosrenol			C	Oral	750 Mg, Q12h		Not Reported
	Metamizole			C	Oral	575 Mg, Q8h		Not Reported
	Tacrolimus			C	Oral	2 Mg, Qd		Not Reported
	Tacrolimus			C	Oral	1 Mg, Qd		Not Reported

	Tacrolimus		C	Oral	2 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17931149	EXPEDITED (15-DAY)		HO, OT	ES-ASTELLAS-2020US020847		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Drug Interaction; Mixed Liver Injury	Tacrolimus			S	Oral			Astellas
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17931455	EXPEDITED (15-DAY)		HO	NVSC2020ES173505		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Novartis
	Azithromycin			S				Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (400 Mg Dia)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17933237	EXPEDITED (15-DAY)		CA	NVSC2020DE175016			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Prednisolone			S	Transplacental	Maternal Dose: Unk		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unk		Not Reported
	Sulfasalazine			S	Transplacental	Maternal Dose: Unk		Not Reported
	Certolizumab			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17936390	EXPEDITED (15-DAY)		OT	TN-PFIZER INC-2020238959			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Azithromycin			S		500 Mg, (On D1)		Pfizer
	Azithromycin			S		250 Mg, (From D2 To D5)		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17936391	EXPEDITED (15-DAY)		OT	TN-PFIZER INC-2020238917			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia	Azithromycin			S		500 Mg (On D1)		Pfizer
	Azithromycin			S		250 Mg (From D2 To D5)		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day (For 10 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17936392	EXPEDITED (15-DAY)		OT	TN-PFIZER INC-2020238944			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Azithromycin			S		500 Mg, (On Day 1)		Pfizer
	Azithromycin			S		250 Mg, (From D2 To D5)		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17936393	EXPEDITED (15-DAY)		OT	TN-PFIZER INC-2020238889			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia	Azithromycin			S		500 Mg (On D1)		Pfizer
	Azithromycin			S		250 Mg (From D2 To D5)		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day (For 10 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17944632	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	200 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945010	EXPEDITED (15-DAY)		OT	CA-ACCORD-186280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S	Unknown			Accord

Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia	S	Unknown		Not Reported
	Actemra	S		Not Specified	Not Reported
	Arava	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Lyrica	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	Not Specified	Not Reported
	Piroxicam	C		Not Specified	Not Reported
	Prednisone	C		Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945060	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-030270		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebral Venous Thrombosis; Disseminated Intravascular Coagulation; Drug Interaction; Dyspnoea; Headache; Hemiparesis; Mental Disorder; Off Label Use; Product Use In Unapproved Indication; Pulmonary Artery Thrombosis; Vena Cava Thrombosis	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Oxygen			S	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945094	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-026970		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash Morbilliform	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Clexane			S	Subcutaneous	8000 Kilo-International Unit, Once A Day		Not Reported
	Fidato			S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day		Not Reported
	Kaletra			S	Oral	4 Dosage Form, Once A Day		Not Reported
	Plaquenil			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Roactemra			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Urbason			S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945781	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052458			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination	Azithromycin			S	Oral	Unk		Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	Unk		Not Reported
	Interferon Beta-1b			S	Unknown	250 Milligram		Not Reported
	Enoxaparina			C				Not Reported
	Kaletra			C	Unknown	Unk		Not Reported
	Genvoya			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945943	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251608		50 YR	Female	ESP

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

Diarrhoea; Hepatitis; Hypertriglyceridaemia	Azithromycin	S	Oral	500 Milligram, Daily	Sun
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	1 Gram, Daily	Not Reported
	Hidroxicloroquina Sulfato (2143su)	S	Oral	400 Milligram, Daily	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Milligram, Bid	Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...	S	Oral	2 Dosage Form, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945946	EXPEDITED (15-DAY)		LT, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251611		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram, Daily		Not Reported
	Rezolsta 800 Mg / 150 Mg Comprimidos Recubiertos Con Pelicula 30 Co...			S	Oral	1 Dosage Form, Daily		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			S	Oral	2 Dosage Form, Daily		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Milligram, Daily		Not Reported
	Interferon Beta-1b (2305od)			S	Subcutaneous	30 Microgram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945950	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048826		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling;	Orencia			S	Unknown			Bristol Myers Squibb

Pain; Red Blood Cell Sedimentation Rate Abnormal	Actemra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17945960	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048808		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis; Therapeutic Response Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported

	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil [Allopurinol]	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946018	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619860		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported
	Golimumab			S	Unknown			Not Reported

Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone	S	Oral	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S		Not Reported
	Topicort [Desoximetasone]	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous	Not Reported

	Tofacitinib Citrate	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946038	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202006006645			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Shock Haemorrhagic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Daily		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946101	NON-EXPEDITED			US-AMGEN-USASP2020075565		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946304	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Retinopathy; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Once Every 4 Weeks	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Codeine	C	Unknown		Not Reported
	Demerol	C	Unknown		Not Reported
	Enbrel	C	Subcutaneous		Not Reported
	Humira	C	Subcutaneous	Once Every 2 Weeks	Not Reported
	Morphine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946357	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946429	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2020-050950

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946435	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-030527			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Delivery; Pulmonary Alveolar Haemorrhage	Azithromycin			S	Transplacental	Unk		Aurobindo
	Aspirin			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	Unk		Not Reported
	Ceftriaxone			S	Transplacental	Unk		Not Reported

	Hydroxychloroquine	S	Transplacental	Unk		Not Reported
	Norepinephrine	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17946507	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-031021		33 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticaria	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Cefixime			S	Oral	400 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported
	Deltacortene			S	Oral	5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17947499	EXPEDITED (15-DAY)		LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251682		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1000 Milligram, Daily		Not Reported
	Rezolsta 800 Mg / 150 Mg Comprimidos Recubiertos Con Pelicula 30 Co...			S	Oral	1 Dosage Form, Daily		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Milligram, Daily		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			C	Oral	2 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17947545	EXPEDITED (15-DAY)		OT	CA-ROCHE-2629061		61 YR	Female	CAN

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

Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Asa	S	Unknown	Not Reported
	Calcium Carbonate	S	Unknown	Not Reported
	Fosinopril	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Synthroid	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948046	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-20881			Female	CAN

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

	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948601	EXPEDITED (15-DAY)		HO	IT-ROCHE-2629588		65 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Off Label Use; Rash	Kaletra			S	Unknown	Most Recent Dose Prior To Ae 27/Mar/2020		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Most Recent Dose Prior To Ae 01/Apr/2020		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948682	EXPEDITED (15-DAY)		HO	ES-ACCORD-186441		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Drug Interaction; Mixed Liver Injury	Metoclopramide			S	Intravenous (not otherwise specified)			Accord
	Tacrolimus			S	Oral			Accord
	Azithromycin			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948753	EXPEDITED (15-DAY)		OT	CA-ROCHE-2628763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis;	Actemra			S	Unknown			Not Reported

Treatment Failure	Cimzia	S	Subcutaneous	Single Use, Pre-Filled Syringe		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Enbrel	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948759	EXPEDITED (15-DAY)		HO	ES-VELOXIS PHARMACEUTICALS-2020VELES-000577		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Mixed Liver Injury	Envarsus			S	Oral	8 Milligram, Qd		Chiesi
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Milligram, Qd		Not Reported
	Metoclopramida [Metoclopramide]			S	Intravenous (not otherwise specified)	10 Milligram, Q12h		Not Reported
	Prednisona			S	Oral	20 Milligram, Qd		Not Reported
	Azitromicina			S	Oral	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948826	EXPEDITED (15-DAY)		CA	FR-MYLANLABS-2020M1058765			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Congenital	Leflunomide			S	Transplacental	Unk		Not Reported

Cystic Kidney Disease; Congenital Renal Disorder; Foetal Exposure During Pregnancy	Prednisone		S	Transplacental	Unk	Not Reported
	Hydroxychloroquine		S	Transplacental	Unk	Mylan
	Levothyroxine Sodium		S	Transplacental	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948992	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1791447		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Azitromicina (7019a)			S	Oral	500 Milligram		Not Reported
	Micafungina Sodica (8263so)			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Milligram		Teva
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)			Not Reported
	Sulfametoxazol + Trimetoprima			S	Oral			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosageform		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949050	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance; Intentional Product Use Issue	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949305	NON-EXPEDITED			US-TEVA-2020-US-1791624			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Actavis			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949408	EXPEDITED (15-DAY)		HO	NVSC2020ES173826		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hydroxychloroquine Sulfate			S	Oral	400 Mg Dia		Novartis
	Paracetamol			S	Intravenous (not otherwise specified)	1gr Cada 8 Horas		Not Reported
	Azitromicina			S	Oral	500 Mg Dia		Not Reported
	Azitromicina			S				Not Reported
	Metamizol			S	Intravenous (not otherwise specified)	2gr Cada 6 Horas		Not Reported
	Tocilizumabum			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949421	NON-EXPEDITED			US-ADVANZ PHARMA-202006006718			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Pain; Headache; Hyperhidrosis; Off Label Use	Pilocarpine			S	Oral	15 Mg, Prn (7.5 Mg At Bedtime, 7.5 Mg At Night)		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid (200 Mg In The Morning And 200mg In The Evening)		Concordia
	Sertraline Hcl			S		100 Mg, Qd (Morning),		Not Reported

Generic

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949642	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020243352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Codeine			S	Unknown	Unk		Pfizer
	Ibuprofen			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	10 Mg, 1x/Day		Not Reported
	Rosuvastatin Calcium			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949650	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1791451		46 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Liver Function Test Abnormal	Azitromicina (7019a)			S	Unknown			Not Reported
	Hidroxicloroquina (2143a)			S	Unknown			Teva
	Ceftriaxona (501a)			S	Unknown			Not Reported
	Interf - Interferon (Sin Especificar)			S	Unknown			Not Reported
	Lopinavir+Ritonavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949836	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1791449		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported

	Hidroxicloroquina Sulfato (2143su)	S	Oral	400 Mg		Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid	S	Oral	2 Df		Not Reported
	Ceftriaxona (501a)	C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949838	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1791445		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Drug Interaction; Mixed Liver Injury	Tacrolimus (2694a)			S	Oral	8 Mg		Not Reported
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Prednisona (886a)			S	Oral	20 Mg		Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950108	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES179110		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis	Azitromicina			S	Oral	500 Mg, Q24h (500 Mg Dia)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Q24h (400 Mg Dia)		Novartis
	Hydroxychloroquine			S				Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950120	EXPEDITED (15-DAY)		HO	NVSC2020ES178832		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Pulmonary Embolism	Hydroxychloroquine			S	Oral	400 Mg		Novartis
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Azitromicina			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950469	EXPEDITED (15-DAY)		DE, OT	NVSC2020DE180082		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Q12h		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Intravenous (not otherwise specified)	1-0-0		Not Reported
	Azithromycin			S				Not Reported
	Tazobac			C	Unknown	Unk		Not Reported
	Tazobac			C				Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Meropenem			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950533	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1057911		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Qd (120 Tablets)		Mylan
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950545	EXPEDITED (15-DAY)		LT	NVSC2020ES179762		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intrusive Thoughts; Suicide Attempt	Hydroxychloroquine			S	Oral	200 Mg, Q8h (200mg Every 12 Hrs)		Novartis
	Levofloxacin			C	Unknown	Unk		Not Reported
	Cortic			C	Intravenous bolus	Unk		Not Reported
	Septrin			C	Unknown	Unk		Not Reported
	Kaletra			C	Oral	Unk		Not Reported
	Acetilcisteina			C	Unknown	Unk		Not Reported
	Ciclosporina			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1793959			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Atorvastatin Calcium			S	Oral	40 Milligram Daily;		Teva
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Sns-Asa Ec			C	Oral	81 Milligram Daily;		Not Reported
	Vitamin D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950667	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1058081		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Sulfametoxazol + Trimetoprima			S	Oral	Unk		Mylan
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan
	Micafungina			S	Intravenous (not otherwise specified)	Unk		Mylan
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950668	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1058072		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hyperbilirubinaemia; Off Label Use	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Bid		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	200 Milligram, Bid		Mylan
	Alopurinol			C	Oral	100 Milligram, Qd		Mylan
	Simvastatina			C	Oral	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950670	EXPEDITED (15-DAY)		OT	NVSC2020ES173706		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (Dia)		Novartis
	Hydroxychloroquine Sulfate			S				Novartis
	Paracetamol			S	Oral	1 G, Q8h (1gr Cada 8h)		Not Reported

	Azitromicina	S	Oral	500 Mg, Qd (Dia)		Not Reported
	Azitromicina	S				Not Reported
	Dexketoprofen Trometamol	S	Intravenous (not otherwise specified)	25 Mg, Q8h (25 Mg Cada 8 Horas)		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950681	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1058080		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Drug Interaction; Mixed Liver Injury; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Tacrolimus			S	Oral	8 Milligram, Qd		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Milligram, Qd		Mylan
	Prednisona			S	Oral	20 Milligram, Qd		Mylan
	Metoclopramida /00041901/			S	Intravenous (not otherwise specified)	10 Milligram, Bid		Mylan
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950687	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1058078		46 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Liver Function Test Abnormal; Off Label Use	Azithromycin			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Ceftriaxona /00672201/			S	Unknown			Mylan
	Interferon			S	Unknown	Unk		Mylan
	Hidroxicloroquina /00072601/			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951146	NON-EXPEDITED			US-SA-2020SA160766			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Use In Unapproved Indication	Dupixent			S	Subcutaneous	300 Mg, Qow		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951273	EXPEDITED (15-DAY)		LT	NVSC2020ES180579		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Interferon Beta			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Cyclosporine			C	Unknown	Unk		Not Reported
	Lopinavir			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ritonavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951278	EXPEDITED (15-DAY)		HO	NVSC2020ES177324		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Amoxicilina + Clavulanato De Potassio			S	Intravenous (not otherwise specified)	1 G, Q8h		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Not Reported
	Hydroxychloroquine			S				Not Reported
	Enoxaparina			S	Subcutaneous	80 Mg, Q24h		Not Reported
	Ceftazidima			S	Intravenous (not otherwise specified)	2 G, Q8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951305	EXPEDITED (15-DAY)		LT	NVSC2020ES180948		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			C	Unknown	Unk		Not Reported
	Cyclosporine			C	Unknown	Unk		Not Reported
	Mycophenolic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951398	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1791217		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hyperbilirubinaemia	Hidroxicloroquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral			Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido			S	Oral	1 Dosage Forms		Not Reported
	Alopurinol 100 Mg 100 Comprimidos			C	Oral	100 Mg		Not Reported
	Simvastatina 10 Mg 28 Comprimidos			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951525	EXPEDITED (15-DAY)		DE, OT	FR-SA-2020SA163954			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Plaquenil			S	Oral			Sanofi
	Azithromycin			S				Not Reported
	Enoxaparin Sodium			S				Sanofi
	Hydroxyzine Hydrochloride			S				Not Reported
	Irbesartan			C				Not Reported
	Propranolol			C				Not Reported

	Etomidate Lipuro	C	Intravenous (not otherwise specified)	Not Reported
	Suxamethonium	C	Intravenous (not otherwise specified)	Not Reported
	Morphine Sulfate	C	Intravenous (not otherwise specified)	Not Reported
	Cefotaxime [Cefotaxime Sodium]	C		Not Reported
	Pregabaline	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951543	EXPEDITED (15-DAY)		DS	CA-ROCHE-2619878		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Topicorten	S	Cutaneous	Not Reported
Salazopyrina	C	Unknown	Not Reported
Atasol With Codeine-Caffeine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951554	EXPEDITED (15-DAY)		OT	NVSC2020FR179737		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Amlodipine Besilate,Valsartan			S	Oral	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951600	EXPEDITED (15-DAY)		HO	CA-ROCHE-2628554		60 YR	Female	CAN

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

Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Injection Site Erythema; Injection Site Induration; Injection Site Inflammation; Injection Site Pruritus; Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Actemra	S	Subcutaneous	Therapy Duration: 1825.0 Days	Not Reported
	Arava	S	Oral	Therapy Duration: 31.0 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Therapy Duration: 100.0 Days	Not Reported
	Methotrexate	S	Oral	Therapy Duration: 44.0 Days	Not Reported
	Quetiapine Fumarate	S	Unknown		Not Reported
	Alendronate Sodium	C			Not Reported
	Amlodipine	C			Not Reported
	Ativan	C			Not Reported
	Lipitor	C			Not Reported
	Methadone	C			Not Reported
	Pantoloc [Pantoprazole]	C			Not Reported
	Prednisone	C			Not Reported
	Valtrex	C			Not Reported
	Zopiclone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951727	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1793910		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Atorvastatin Calcium			S	Unknown	10 Milligram Daily;		Teva
	Alendronate Sodium			S	Unknown			Actavis
	Furosemide			S	Unknown	40 Milligram Daily;		Not Reported
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva
	Metformin			S	Oral	1000 Milligram Daily;		Actavis

Prednisone	S	Unknown	5 Milligram Daily;		Actavis
Atrovent	S	Unknown			Not Reported
Flovent	S	Unknown			Not Reported
Lipitor	S	Unknown	10 Milligram Daily;		Not Reported
Losec [Omeprazole Magnesium]	S	Oral	20 Milligram Daily;		Not Reported
Nitrazadon	S	Unknown	10 Milligram Daily;		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram Daily;		Not Reported
Salmeterol Xinafoate	S	Unknown			Not Reported
Tylenol	S	Unknown	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951737	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048858		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	4 Milligram/Kilogram		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951876	EXPEDITED (15-DAY)		HO, LT	NVSC2020ES180570		38 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Bid		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Bid		Novartis
	Mycophenolic Acid			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951895	EXPEDITED (15-DAY)		OT	NVSC2020US178788		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Product Use In Unapproved Indication; Scleroderma	Methotrexate			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Triamcinolone			S		Unk		Not Reported
	Vit D			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048842		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb

Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Hypersensitivity; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia	S	Unknown	750 Milligram	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q12h	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Q12h	Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown	4 Milligram, Q6h	Not Reported
	Diphenhydramine	C	Unknown		Not Reported
	Dyclonine Hydrochloride	C	Unknown		Not Reported
	Furosemide	C	Unknown	40 Milligram, Q8h	Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown		Not Reported
	Loperamide Hydrochloride	C	Unknown	Unk Unk, Q12h	Not Reported
	Morphine Sulfate	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported

Orphenadrine Citrate	C	Unknown	Unk Unk, Q12h		Not Reported
Oxyneo	C	Unknown			Not Reported
Pantoprazole	C	Unknown			Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown			Not Reported
Restasis	C	Unknown			Not Reported
Synthroid	C	Unknown			Not Reported
Trimethoprim	C	Unknown			Not Reported
Urispas	C	Unknown			Not Reported
Vagifem	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951994	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049161		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations	Orencia			S	Intravenous (not otherwise specified)	500 Milligram		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Milliequivalent		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Coversyl [Perindopril Erbumine]			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952007	EXPEDITED (15-DAY)		OT	CA-ROCHE-2628637			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Januvia [Sitagliptin]			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952098	EXPEDITED (15-DAY)		OT	NVSC2020FR178532			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	600 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952100	EXPEDITED (15-DAY)		OT	NVSC2020FR178534			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	600 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952102	EXPEDITED (15-DAY)		HO	NVSC2020IT180057		68 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19;	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis

General Physical Health Deterioration; Interstitial Lung Disease; Product Use In Unapproved Indication	Prednisone		S	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952129	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952381	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049235		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain;	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Pemphigus; Swelling; Systemic Lupus Erythematosus	Cetirizine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952498	EXPEDITED (15-DAY)		OT	NVSC2020IT152384		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Teicoplanin			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Haloperidol			S	Oral	5 Gtt, Qd		Not Reported
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952513	EXPEDITED (15-DAY)		HO	NVSC2020ES177249		79 YR	Female	ESP

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

Hepatitis	Hydroxychloroquine	S	Oral	400 Mg, Qd (400 Mg Dia)	Novartis
	Hydroxychloroquine	S			Novartis
	Colchicine	S	Oral	1 Df, Q12h (1 Ud De Y Ce)	Not Reported
	Colchicine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952518	EXPEDITED (15-DAY)		OT	NVSC2020ES180061		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Hydroxychloroquine			S	Oral	400 Mg, Q12h		Novartis
	Lopinavir + Ritonavir			S	Oral	Unk Unk, Q12h		Not Reported
	Azithromycin			C	Unknown	500 Mg, Q24h		Not Reported
	Bemiparin			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Enalapril			C	Oral	20 Mg, Q24h		Not Reported
	Janumet			C	Oral	1 Df, Q12h		Not Reported
	Sintrom			C	Unknown	2 Mg, Q24h (4 Mg Comprimidos)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952687	EXPEDITED (15-DAY)		OT	NVSC2020ES177745		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azithromycin			S	Oral	Unk (500 Mg Dia)		Novartis
	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported
	Dexamethason			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

	Enoxaparina	S	Subcutaneous	80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952749	EXPEDITED (15-DAY)		HO	NVSC2020ES177608		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Azitromicina			S	Oral	500 Mg, Qd (Dia)		Not Reported
	Azitromicina			S				Not Reported
	Colchicina			S	Oral	1 U (Desayuno)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg (Total)		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952764	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES177706		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Unknown	400 Mg, Q24h (Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Colchicina			S	Oral	0.5 Mg, Q12h (Cada)		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, 1 Total		Not Reported
	Roactemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	16872434	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2412613		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not	Cyclical		Not Reported

Antibody Positive; Arthritis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Operation; Gastroenteritis Viral; Hand Deformity; Hypertension; Hypocalcaemia; Hypokalaemia; Hypotension; Ill-Defined Disorder; Immunodeficiency; Infection; Intentional Product Use Issue; Joint Destruction; Limb Discomfort; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Nausea; Nodule; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Psoriasis; Pulmonary Fibrosis; Pyrexia; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Rituxan	S	otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported

Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Actonel	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Apo-Naproxen	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Naproxen	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported

Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Triamcinolone	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Not Reported
Risedronate Sodium	S	Unknown	Not Reported
Risedronate	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Folic Acid	C		Not Reported
Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17919285	EXPEDITED (15-DAY)		HO	NVSC2020ES171662		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Azithromycin			S				Novartis
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17952903	EXPEDITED (15-DAY)		OT	CA-ACCORD-187240		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use;	Mycophenolic Acid			S				Not Reported
	Methotrexate			S				Accord
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Eljanz		C	otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17952931	EXPEDITED (15-DAY)		DE, OT	IT-ACCORD-187043		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukocytosis; Pyrexia; Respiratory Distress; Sepsis	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Intravenous (not otherwise specified)			Accord
	Acetylsalicylic Acid			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Tirofiban/Tirofiban Hydrochloride			S	Intravenous bolus	25 Microg/Kgbody		Not Reported
	Fondaparinux			S	Subcutaneous	2.5 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	1 Mg/Kg		Not Reported
	Tirofiban/Tirofiban Hydrochloride			S	Intravenous bolus	0.15 Microg/Kgbody Per Minute For 48 Hours		Not Reported
	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Not Reported
	Clopidogrel			S	Oral	300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17952993	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020024050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme	Cimzia			S		Unk		Not Reported
	Arthrotec			S				Not Reported
	Cosentyx			S		Unk		Not Reported
	Cosentyx			S				Not Reported
	Enbrel			S				Not Reported

Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Humira	S	Subcutaneous			Not Reported
	Leflunomide	S				Not Reported
	Lipitor	S	Oral			Not Reported
	Methotrexate	S				Not Reported
	Methotrexate	S		12.5 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
	Sulfasalazine	S				Not Reported
	Dovobet	C	Topical			Not Reported
	Flovent	C				Not Reported
	Folic Acid	C	Oral			Not Reported
	Multi Vitamin [Ascorbic Acid;Colecalciferol;Nicotinamide; Panthenol;Pyr	C	Oral			Not Reported
	Omeprazole	C	Oral			Not Reported
	Ventoline [Salbutamol]	C				Not Reported
	Vitamin D2	C	Oral	1000 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953145	EXPEDITED (15-DAY)		OT	NVSC2020JP180910			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Tacrolimus			S	Transplacental	Unk (Maternal Dose: 3 Mg Qd)		Novartis
	Methylprednisolone			S	Transplacental	Unk (Maternal Dose: 0.5 G Daily For 3 Days)		Not Reported
	Prednisolone			S	Transplacental	Unk, 45 Mg Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk, (Maternal Dose: 200 Mg)		Not Reported
	Aspirin			S	Transplacental	Unk (Maternal Dose: 100 Mg)		Not Reported
	Low Molecular Weight Heparin			S	Transplacental	Unk (Maternal Dose: 10,000 U Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953146	EXPEDITED (15-DAY)		HO	NVSC2020ES177487		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd (2 Gr Dia)		Not Reported
	Ceftriaxona			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953153	EXPEDITED (15-DAY)		OT	NVSC2020ES177563		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd (2 Gr)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953156	EXPEDITED (15-DAY)		OT	NVSC2020ES180020			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	500 Mg, Q24h		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Q24h		Not Reported

	Roactemra	S	Intravenous (not otherwise specified)	600 Mg (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953157	EXPEDITED (15-DAY)		OT	NVSC2020ES177493		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h (400 Mg Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	500 Mg, Q24h (500 Mg Dia)		Not Reported
	Enoxaparina			S	Subcutaneous	40 Mg, Q24h (40 Mg Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953159	EXPEDITED (15-DAY)		OT	NVSC2020ES177520		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Once/Single (600 Mg Dia)		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953164	EXPEDITED (15-DAY)		HO	NVSC2020ES177719		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis
	Privigen			S	Intravenous (not otherwise specified)	32 G, Q24h		Not Reported
	Roactemra			S	Intravenous (not	600 Mg, Q24h		Not Reported

					otherwise specified)					
	Azithromycin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953168	EXPEDITED (15-DAY)		HO	NVSC2020ES177771		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree	Hydrocortisone			S	Intravenous (not otherwise specified)	200 Mg, Q24h		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953195	EXPEDITED (15-DAY)		OT	NVSC2020ES177555		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h (400 Mg Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	500 Mg, Q24h (500 Mg Dia)		Not Reported
	Enoxaparina			S	Subcutaneous	40 Mg, Q24h (40 Mg Dia)		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Q24h (2 Gr Dia)		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Once/Single		Not Reported
	Roactemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953198	EXPEDITED (15-DAY)		HO	NVSC2020ES177277		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	800 Mg, Qd		Novartis

	Hydroxychloroquine		S	Oral	400 Mg, Qd	Novartis
	Ivermectin		S	Oral	12 Mg, Total	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg, Total	Not Reported
	Tocilizumab		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953219	EXPEDITED (15-DAY)		HO	NVSC2020ES177417		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Dia)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Once/Single		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953221	EXPEDITED (15-DAY)		OT	NVSC2020ES177582		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h (400 Mg Dia)		Novartis
	Azithromycin			S	Oral	500 Mg, Q24h (500 Mg Dia)		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Once/Single		Not Reported
	Roactemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17953233	EXPEDITED (15-DAY)		OT	NVSC2020IT150078		75 YR	Male	ITA

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

Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin		S	Oral	500 Mg, Qd	Novartis
	Plaquenil		S	Oral	600 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17956546	DIRECT		DS			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Complaint; Product Substitution Issue; Pruritus; Rash	Hydroxychloroquine 200mg			S	Oral	Quantity:180 Tablet(S);		Dr Reddys
	Humira			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C				Not Reported
	Gabapentin			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D			C				Not Reported
	Calcium			C				Not Reported
	Cranberry Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17953409	EXPEDITED (15-DAY)		OT	NVSC2020ES177287		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg, Q24h (500 Mg Dia)		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Q24h (400 Mg Dia)		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17953470	EXPEDITED (15-DAY)		OT	NVSC2020ES177285		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg, Q24h (500 Mg Dia)		Novartis

	Azithromycin	S				Novartis
	Hydroxychloroquine	S	Oral	400 Mg, Q24h (400 Mg Dia)		Not Reported
	Hydroxychloroquine	S				Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg, Once/Single		Not Reported
	Enoxaparina	S	Subcutaneous	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17953473	EXPEDITED (15-DAY)		HO	NVSC2020ES177752		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Vessel Puncture Site Haemorrhage	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Qd (20 Mg Dia)		Not Reported
	Enoxaparina			S	Subcutaneous	40 Mg, Qd		Not Reported
	Acetilsalicilato De Lisina			S	Intravenous (not otherwise specified)	200 Mg, Once/Single		Not Reported
	Adiro			S	Oral	100 Mg, Qd (1 Cp Dia 100 Mg Comprimidos Gastrorresistentes Efg, 500 Comprimidos)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17953499	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA054621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Vitamin B1			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Novartis
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Qmo		Not Reported

Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Celebrex	S	Occlusive dressing technique	Unk	Not Reported
	Gabapentin	S	Oral	100 Mg, Bid	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Q3w	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Omega 3	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q3w	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Fumarate	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Lomotil	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk (Spray, Metered Dose)	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported

Thiamine Hydrochloride	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Vitamin A	C	Unknown	Unk		Not Reported
Vitamin B3	C	Unknown	Unk		Not Reported
Vitamin B 12	C	Unknown	Unk		Not Reported
Vitamin B6	C	Unknown	Unk		Not Reported
Vitamiin C	C	Unknown	Unk		Not Reported
Vitamiin E	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17953587	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3456869-00			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Inflammation; Malaise; Off Label Use; Pneumonia; Pulmonary Embolism	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	12370677	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-1756598		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Breath Sounds Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 365 Nos		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown Dose And Frequency, Discontinued		Not Reported
	Enbrel			S	Subcutaneous	Unknown Dose And Frequency		Not Reported

Daily Activities; Off Label Use; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	End Date: Unknown	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Alprazolam	C	Unknown		Not Reported
	Amlodipine	C	Unknown		Not Reported

Arava	C	Unknown	Not Reported
Bisoprolol Fumarate	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Iron Sucrose	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Paroxetine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Intracardiac	Not Reported
Risedronate	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported
Simvastatin	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Telmisartan	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	14516779	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2250003-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Blindness; Bone Disorder; General Physical Condition Abnormal	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	16080945	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013872		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Rosuvastatin			S	Oral	5 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported
	Cephalexin			C	Unknown	500 Milligram, Four Times/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	16346220	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028344		62 YR	Female	CAN

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

Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy;	Piperacillin+Tazobactam	S	Unknown	Unk	Aurobindo
	Rosuvastatin Tablet	S	Unknown	Unk	Aurobindo
	Vancomycin Hydrochloride	S	Unknown	Unk	Aurobindo
	Ceftazidime	S	Unknown	Unk	Not Reported
	Furosemide	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	500 Milligram, 2 Every One Day	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Plaquenil	S	Unknown	200 Milligram	Not Reported
	Prednisone	S	Unknown	7.5 Milligram	Not Reported
	Prednisone	S	Unknown	10 Milligram, Once A Day	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Apo Amlo	C	Unknown	Unk	Not Reported
	Apo-K	C	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
	Epoetin Alfa	C	Unknown	Unk	Not Reported
	Escitalopram	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Humalog	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Januvia	C	Unknown	Unk	Not Reported

Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Potassium Chloride		C	Unknown	Unk	Not Reported
	Metformin		C	Unknown	Unk	Not Reported
	Methylprednisolone		C	Unknown	Unk	Not Reported
	Metoprolol		C	Unknown	Unk	Not Reported
	Pantoloc		C	Unknown	Unk	Not Reported
	Risedronate		C	Unknown	Unk	Not Reported
	Slow-K		C	Unknown	Unk	Not Reported
	Tylenol		C	Unknown	Unk	Not Reported
	Ventolin		C	Unknown	Unk	Not Reported
	Apo-Amiodarone		C	Unknown	Unk	Not Reported
	Apo-Ketorolac		C	Unknown	Unk	Not Reported
	Eprex		C	Unknown	Unk	Not Reported
	Pantoprazole		C	Unknown	Unk	Not Reported
	Risedronate Sodium		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17425017	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0812		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Unknown	Therapy Duration 577.0		Not Reported
	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown	Therapy Duration 577.0		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17438913	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007930		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17526182	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07737		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S				Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unknown,Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Minocin			S	Unknown	Unknown		Not Reported
	Minocycline			S	Unknown	Unknown		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unknown		Not Reported
	Myochrysine			S	Parenteral	Unknown,Solution Intramuscular		Not Reported
	Myochrysine			S	Intramuscular	Unknown		Not Reported
	Myochrysine			S	Subcutaneous	Unknown		Not Reported

Orencia	S	Unknown		Not Reported
Otezla	S	Oral	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Parenteral	Unknown	Not Reported
Rituximab	S	Intravenous drip	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown,Solution Subcutaneous	Not Reported
Sirukumab	S	Unknown	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Stelara	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Tofacitinib Citrate	S	Oral		Not Reported
Ustekinumab	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Salazopyrin	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported
Rheumatrex [Methotrexate Sodium]	C	Unknown	Unknown	Not Reported
Salazopyrin	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17547565	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001261			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17663750	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201706-003792			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid,Hydroxychloroquine Sulfate		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Apoleflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Methotrexate Sodium	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Methotrexate	S	Unknown	15 Mg		Not Reported
Leflunomide	S	Oral	10 Mg, Qd		Not Reported
Xeljanz	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported
Simponi	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17786218	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020189472		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Kaletra			S	Oral	2 Df, 2x/Day		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17814831	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Tocilizumab	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Kevzara	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17817135	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020202096		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg		Not Reported
	Kaletra E M			S	Oral	2 Df, 2x/Day (Each 12h)		Not Reported
	Ceftriaxone			S	Intravenous (not	2 G, 1x/Day		Not Reported

			otherwise specified)		
	Enalapril/Hydrochlorothiazide	C	Oral	Unk	Not Reported
	Omeprazole	C	Oral	20 Mg, 2x/Day (Each 12h)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17837105	EXPEDITED (15-DAY)		DE, OT	ES-MYLANLABS-2020M1051992		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S		Unk		Not Reported
	Hidroxicloroquina /00072601/			S		Unk		Mylan
	Metilprednisolona /00049601/			S		Unk		Mylan
	Kaletra			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17842449	EXPEDITED (15-DAY)		DE, HO	SK-ROCHE-2388944		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17846771	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1241465		86 YR	Male	ESP

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

Completed Suicide; Depressed Mood	Hidroxicloroquina (2143a)	S		Teva
	Azitromicina (7019a)	S		Not Reported
	Metilprednisolona (888a)	S		Not Reported
	Kaletra	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17857674	EXPEDITED (15-DAY)		DE, OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051575			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk, Every 48 Hours		Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine]			S	Unknown	Unk		Not Reported
	Kaletra			C	Unknown	Unk		Not Reported
	Kaletra			C				Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17869741	EXPEDITED (15-DAY)		OT	ES-ROCHE-2610743		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Hypofibrinogenaemia; Melaena; Sepsis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Dexametasona [Dexamethasone]			C	Intravenous (not otherwise specified)			Not Reported
	Dexametasona [Dexamethasone]			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17875796	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200609673			Male	CAN

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

Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17875797	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular			Not Reported

Methotrexate	S	Intramuscular		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Plaquenil /00072603/	S	Oral		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17875842	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Dorzolamide Hydrochloride W/Timolol Maleate			C	Ophthalmic			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Timolol Maleate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17875847	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17881782	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609655			Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17881802	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17881804	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Urticaria	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Orencia	S		Not Reported
Acetaminophen	C		Not Reported
Acetylsalicylic Acid	C		Not Reported
Ibuprofen	C		Not Reported
Morphine	C		Not Reported
Pertussis Vaccine	C		Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17887107	EXPEDITED (15-DAY)			SK-ADVANZ PHARMA-202006006297			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Kaletra			C		Unk		Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17901889	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609653			Female	CAN

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

	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17907024	NON-EXPEDITED			US-PFIZER INC-2020234902		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Gait Disturbance; Pain; Post Herpetic Neuralgia	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17931249	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2020FR173259			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17940730	EXPEDITED (15-DAY)		LT	NVSC2020FR177113		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin Monohydrate			S	Oral	Unk		Novartis
	Plaquenil			S	Oropharingeal	200 Mg, Q8h		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17944932	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609679		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17948341	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020240953		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Kaletra			S		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954085	EXPEDITED (15-DAY)		LT, OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052425			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Disorientation; Hyperbilirubinaemia; Liver Function Test Abnormal; Urinary Retention	Levofloxacin			S	Unknown	500 Mg		Zydus Pharm
	Hidroxicloroquina Sulfato			S	Oral	Unk		Not Reported
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	1/24		Not Reported
	Pulmicort			C	Unknown	2 Puff Cada 8 Horas		Not Reported
	Ventolin [Salbutamol]			C		Unk		Not Reported
	Urbason [Methylprednisolone Acetate]			C	Unknown	Unk		Not Reported
	Clexane			C		40/24 Horas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954097	EXPEDITED (15-DAY)		DE, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-251247		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Coma; Condition Aggravated; Dry Gangrene; Off Label Use; Respiratory Failure	Noradrenaline			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Darunavir/Cobicistat			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954142	EXPEDITED (15-DAY)		OT	CA-ACCORD-187236			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Accord

	Mycophenolic Acid	S	Unknown	Accord
	Hydroxychloroquine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954206	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052449			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatitis; Hypertriglyceridaemia	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Ceftriaxon			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Milligram		Not Reported
	Kaletra			S	Oral	2 Dosage Form		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954207	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052457			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Zydus Pharm
	Ceftriaxon			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954208	EXPEDITED (15-DAY)		LT	ES-CADILA HEALTHCARE			Unknown	ESP

LIMITED-ES-ZYDUS-052477

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rezolsta			S	Oral	1 Dosage Form		Not Reported
	Kaletra			S	Oral	2 Dosage Form		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram		Not Reported
	Interferon Beta-1b			S	Subcutaneous	30 Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954213	EXPEDITED (15-DAY)		LT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052456			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Kaletra			C	Oral			Not Reported
	Ceftriaxon			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rezolsta			S	Oral	1 Dosage Form		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954214	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052481			Unknown	ESP

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

Delusional Disorder, Persecutory Type; Mixed Liver Injury	Azithromycin	S	Oral	500 Milligram		Zydus Pharm
	Tacrolimus	S	Oral	8 Milligram		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	800 Milligram		Not Reported
	Prednisone	S	Oral	20 Milligram		Not Reported
	Metoclopramide	S	Intravenous (not otherwise specified)	10 Milligram		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954228	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-030526			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asymptomatic Covid-19; Covid-19; Foetal Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Transplacental	Unk		Aurobindo
	Aspirin			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	Unk		Not Reported
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Norepinephrine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954267	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-030375		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Sulfasalazine			S	Oral	2.5 Milligram, Once A Day		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every Month		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Two Times A Day		Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Arava	S	Oral	20 Milligram, Once A Day	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Every 3 Weeks	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every Month	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, 1 Every Week	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Every Week	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Ferrous Fumarate	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Perphenazine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Pyridoxine	C	Unknown	Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported

Thiamine Hcl	C	Unknown	Unk		Not Reported
Thiamine Mononitrate	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Vitamin A	C	Unknown	Unk		Not Reported
Vitamin C	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954428	EXPEDITED (15-DAY)		HO	IT-ROCHE-2619060		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Covid-19 Pneumonia; Intentional Product Use Issue; Off Label Use	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954599	NON-EXPEDITED			US-ADVANZ PHARMA-202006006390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Night Sweats; Nightmare	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954601	NON-EXPEDITED			US-ADVANZ PHARMA-202006006660			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954619	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202006006720			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Dyspnoea; Off Label Use; Pyrexia; Tachycardia; Tachypnoea	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	30 Mg, Qd		Not Reported
	Rituximab			S	Unknown	In Feb-2020, Completed 4 Weekly Infusions		Not Reported
	Bactrim			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17954895	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-030750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Rosuvastatin			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Arava			S	Unknown	10 Milligram, Once A Day		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17955067	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052448			Unknown	ESP

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

Bradycardia; Long Qt Syndrome	Azithromycin	S	Oral	500 Milligram, Qd		Zydus Pharm
	Azithromycin	S				Zydus Pharm
	Lopinavir/Ritonavir	S	Oral	2 Dosage Form		Not Reported
	Lopinavir/Ritonavir	S				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S	Oral	400mg C/12 Horas Seguido De 200mg C/12 Horas		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S				Not Reported
	Ceftriaxona [Ceftriaxone Sodium]	S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Ceftriaxona [Ceftriaxone Sodium]	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17955100	EXPEDITED (15-DAY)		OT	NVSC2020JP178457		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication	Prednisolone			S	Unknown	45 Mg, Qd		Novartis
	Methylprednisolone			S	Intravenous (not otherwise specified)	0.5 G, Qd For 3 Days		Not Reported
	Tacrolimus			S	Unknown	3 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Aspirin Solution			S	Unknown	100 Mg, Qd		Not Reported
	Low Molecular Weight Heparin			S	Subcutaneous	10000 U, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17955140	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES181849		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Shock	Hydroxychloroquine			S	Unknown			Novartis
	Azithromycin			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

	Lopinavir/Ritonavir	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17955219	EXPEDITED (15-DAY)		LT, OT	ES-TEVA-2020-ES-1792505		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Disorientation; Hyperbilirubinaemia; Liver Function Test Abnormal; Urinary Retention	Hidroxicloroquina (2143a)			S	Oral	800 Mg 1 Day + 400 Mg The Rest		Teva
	Levofloxacino (2791a)			S		1000 Milligram Daily;		Teva
	Lopinavir+Ritonavir			S		200/20 Four Times A Day		Not Reported
	Omeprazol (2141a)			C		1/24		Not Reported
	Pulmicort			C		6 Dosage Forms Daily; 2 Puff Every 8 Hours		Not Reported
	Ventolin			C				Not Reported
	Urbason			C		40 Mg First Every 8 Hours, At 5 Days Every 12		Not Reported
	Clexane			C		40/24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17955632	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-031606		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Dolquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Methylprednisolone			S	Unknown	40 Milligram, Once A Day (Día 1: Bolo De 80mg, Del 08/04 Al 16/04 En Pauta Descendente)		Not Reported

	Clexane	C	Unknown	Unk		Not Reported
	Metamizole	C	Unknown	Unk		Not Reported
	Metoclopramide	C	Unknown	Unk		Not Reported
	Omeprazol	C	Unknown	Unk		Not Reported
	Paracetamol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956049	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1791841		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S				Teva
	Kaletra			S				Not Reported
	Metilprednisolona (888a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956172	EXPEDITED (15-DAY)		OT	CA-ACCORD-185748		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednison			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone			S	Unknown	Ointment		Not Reported

Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	1 Every 1 Days	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Salazopyrine	S	Oral	2 Every 1 Days	Not Reported
	Sarilumab	S			Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Stelara	S			Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S			Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Topicort Lp	S	Subcutaneous		Not Reported
	Winpred	S	Oral		Not Reported
	Xeljanz	S			Not Reported
	Tofacitinib	C			Not Reported
	Cetirizine	S	Unknown		Not Reported

Cetirizine	S	Unknown			Not Reported
Cetirizine	S	Unknown			Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Cimzia	S	Unknown	Single-Use Prefilled Syringe		Not Reported
Diclofenac	S	Unknown			Not Reported
Folic Acid	S	Unknown			Not Reported
Folic Acid	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown	1 Every 1 Days		Not Reported
Hydroxychloroquine	S	Unknown	1 Every 1 Days		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Accord
Methotrexate	S	Oral	1 Every 1 Days		Accord
Methotrexate	S	Oral			Accord
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Unknown			Not Reported
Rituximab	S	Subcutaneous			Not Reported
Golimumab	S	Subcutaneous			Not Reported
Golimumab	S				Not Reported
Golimumab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral	1 Every 1 Days		Not Reported
Topicort Lp	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956173	EXPEDITED (15-DAY)		OT	CA-ACCORD-185906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue;	Methotrexate			S	Unknown			Not Reported

Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone/Prednisone Acetate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956236	EXPEDITED (15-DAY)		HO	FR-ACCORD-187119		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pustular	Atenolol/Atenolol Hydrochloride			S	Oral			Accord
	Allopurinol			S	Oral			Accord
	Atorvastatin/Atorvastatin Calcium			S	Oral			Not Reported
	Furosemide			S	Oral			Accord
	Lantus			S	Subcutaneous			Not Reported
	Novorapid			S	Subcutaneous			Not Reported

	Advagraf	S	Oral	Strength: 1 Mg	Not Reported
	Cortancyl	S	Oral	Strength: 5 Mg	Not Reported
	Azithromycin	S	Oral		Not Reported
	Flecaine	S	Oral	Strength: 100 Mg, Scored Tablet	Not Reported
	Aranesp	S	Subcutaneous		Not Reported
	Colecalciferol	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Loxen L P	S	Oral	Strength: 50 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956408	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-187269			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956409	EXPEDITED (15-DAY)		OT	CA-ACCORD-187271		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Off Label Use; Placental Insufficiency; Premature Delivery	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956477	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-20854		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Poor Venous Access; Product Use In Unapproved Indication; Product Use Issue;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Immunoglobulins			S	Intravenous (not			Not Reported

Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	[Immunoglobulins Nos]		otherwise specified)			
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen	S	Unknown	Unknown		Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous drip			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Unknown			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown, Suspension Intra Articular		Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown		Not Reported
	Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956511	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1793297		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haematotoxicity; Hypokalaemia; Muscular Weakness; Nausea; Overdose; Somnolence; Suicide Attempt; Toxicity To Various Agents; Ventricular Tachycardia; Vomiting	Hydroxychloroquine			S	Oral	200mg 20 Tablets		Teva
	Hydroxychloroquine			S				Teva
	Methotrexate			S	Oral	2.5mg 30 Tablets		Barr
	Methotrexate			S				Barr
	Prednisone			S	Oral	10mg 30 Tablets		Actavis
	Prednisone			S				Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956926	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-030877		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pustular	Atenolol			S	Oral	50 Milligram, Once A Day		Aurobindo
	Atorvastatin			S	Oral	20 Milligram, Once A Day		Not Reported
	Allopurinol			S	Oral	300 Milligram, Once A Day		Not Reported
	Azithromycin			S	Oral	Unk		Aurobindo
	Cholecalciferol			S	Oral	Unk		Not Reported
	Furosemide			S	Oral	120 Milligram, Once A Day		Aurobindo
	Lantus			S	Subcutaneous	Unk		Not Reported
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Advagraf			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Cortancyl			S	Oral	7.5 Milligram, Once A Day		Not Reported
	Flecaine			S	Oral	100 Milligram, Once A Day		Not Reported
	Aranesp			S	Subcutaneous	40 Microgram, Every Week		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Loxen L P			S	Oral	100 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957466	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1793413		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Unknown	800 Milligram Daily; On Day 1.		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957586	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048322			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram		Glenmark
	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark
	Fentanyl			S	Unknown	Unk		Not Reported
	Nortriptyline			S	Oral	10 Milligram		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram (1 Every One Month)		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qw		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Od (1 Every 24 Hours)		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw (1 Every 1 Week)		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram (1 Every 3 Weeks)		Not Reported
	Myochrysine			S	Unknown	60 Milligram (1 Every 3 Weeks)		Not Reported
	Orencia			S	Vaginal	750 Milligram (1 Every 1 Month)		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Od (1 Every 24 Hours)		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Lomotil /00034001/			C	Unknown	Unk		Not Reported
	Loperamide			C	Unknown	Unk		Not Reported

Nasonex	C	Unknown	Unk		Not Reported
Esomeprazole Magnesium	C	Unknown	Unk		Not Reported
Oxycodone Terephthalate	C	Unknown	Unk		Not Reported
Pantoprazole Magnesium	C	Unknown	Unk		Not Reported
Perphenazine	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported
Esomeprazole	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Omega 3 /06850301/	C	Unknown	Unk		Not Reported
Trazodone Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957734	EXPEDITED (15-DAY)		DE, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051358			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Reyataz			S	Oral	400 Mg Daily		Bristol Myers Squibb
	Paracetamol			S	Unknown	500 Mg, "Oral Or Intravenous"		Bristol Myers Squibb
	Plaquenil			S	Oral	400 Milligram (2 Doses)		Not Reported
	Co-Amoxi			S	Intravenous drip	2.2 Gram In Total		Not Reported
	Tazobac			S	Intravenous drip	4.5 Gram, Every 3 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957743	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050873			Male	CAN

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

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Orencia	S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia	S				Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Actemra	S				Not Reported
	Anakinra	S	Unknown			Not Reported
	Anakinra	S				Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Apo-Leflunomide	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S				Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Ilaris	S	Subcutaneous			Not Reported
	Ilaris	S				Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S				Not Reported
	Sulfasalazine	S	Unknown	500 Milligram		Not Reported
	Sulfasalazine	S				Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957808	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1059201		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use	Magnesium Sulfate			S	Unknown			Not Reported
	Furosemide			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, 12 Hours		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Milligram, Q3h		Mylan
	Methylprednisolone			S	Intravenous (not otherwise specified)	100 Milligram, Qd, After Initial Doses		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Milligram, 1 Dose		Mylan
	Norepinephrine			C	Intravenous drip	8 Microgram, Qminute, Titrated Up To A Maximum Of 20 Microg/Min		Mylan
	Norepinephrine			C	Intravenous drip	20 Microgram, Qminute		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957824	EXPEDITED (15-DAY)		HO	FR-SA-2020SA164979			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash Pustular	Plaquenil			S	Oral			Sanofi
	Plaquenil			S				Sanofi
	Atorvastatin Calcium			S	Oral	20 Mg, Qd		Not Reported
	Lantus			S	Subcutaneous			Sanofi
	Allopurinol			S	Oral	300 Mg, Qd		Not Reported
	Colecalciferol			S	Oral			Not Reported
	Atenolol			S	Oral	50 Mg, Qd		Not Reported
	Furosemide			S	Oral	120 Mg, Qd		Sanofi
	Azithromycin			S	Oral			Not Reported

	Flecainide Acetate	S	Oral	100 Mg, Qd (Breakable Tablet)	Not Reported
	Cortancyl	S	Oral	7.5 Mg, Qd (Compressed)	Not Reported
	Novorapid	S	Subcutaneous		Not Reported
	Advagraf	S	Oral	1 Df, Qd	Not Reported
	Aranesp	S	Subcutaneous	40 Ug, Qw	Not Reported
	Nicardipine	S	Oral	100 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17958223	EXPEDITED (15-DAY)		OT	RU-SA-2020SA165349			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Placental Insufficiency; Premature Baby	Clexane			S	Transplacental	0.4 Unk, Qd		Sanofi
	Clexane			S	Transplacental	0.4 Unk, Bid		Sanofi
	Clexane			S	Transplacental	0.4 Unk, Bid		Sanofi
	Prednisone			S	Transplacental	4 Tablets In The Morning ? 3 Tablets At Noon ? 1 Tablet In The Evening		Not Reported
	Methylprednisolone			S	Transplacental	8 Df, Qd		Not Reported
	Methylprednisolone			S	Transplacental	Sodium Chloride Solution 0.9% - 100.0 Iv Within 30 Min		Not Reported
	Methylprednisolone			S	Transplacental	Sodium Chloride Solution 9%- 100.0 Iv Dri Pn Monday And Thursday		Not Reported
	Plaquenil			S	Transplacental	1 Df, Bid		Sanofi
	Nifedipine			S	Transplacental	30 Mg, Bid		Not Reported
	Nifedipine			S	Transplacental	30 Mg, Qd		Not Reported
	Nifedipine			S	Transplacental	30 Mg, Qd		Not Reported
	Nifedipine			S	Transplacental	60 Mg In The Morning +30 Mg In The Evening		Not Reported
	Methyldopa			S	Transplacental	0.5 Df, Qd		Not Reported

	Methyldopa	S	Transplacental	0.5 Df, Tid	Not Reported
	Methyldopa	S	Transplacental	1.5 Df, Qd	Not Reported
	Methyldopa	S	Transplacental	1.5 Df, Qd	Not Reported
	Omeprazole	S	Transplacental	1 Df, Bid	Not Reported
	Levothyroxine Sodium	S	Transplacental		Not Reported
	Progesterone	S	Transplacental	400 Mg, Qd, From 14 Weeks	Not Reported
	Fosfomycin	S	Transplacental	3 G, Hs	Not Reported
	Fosfomycin	S	Transplacental	3 G, Qw, On Friday	Not Reported
	Dipyridamole	S	Transplacental	75 Mg, Bid	Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Transplacental	1 Df, Tid	Not Reported
	Folic Acid	S	Transplacental	1 Df, Tid	Not Reported
	Cefepime Hydrochloride	S	Transplacental	Unk	Not Reported
	Magnesium Sulfate	S	Transplacental		Not Reported
	Ceftaroline Fosamil	S	Transplacental	600 Mg + Sodium Chloride Solution 0.9% -100.0, Every 12 Hours For 10 Days Iv Slowly! Within An Hour	Not Reported
	Suprastin	S	Transplacental	1 Df, Hs	Not Reported
	Suprastin	S	Transplacental	1 Df, Bid	Not Reported
	Azathioprine	S	Transplacental	50 Mg, Qd, In The Morning	Not Reported
	Azathioprine	S	Transplacental	50 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17958295	EXPEDITED (15-DAY)		OT	NVSC2020FR182296		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17958296	EXPEDITED (15-DAY)		LT, OT	CH-PFIZER INC-2020246029		77 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Electrocardiogram Qt Prolonged; Hyperkalaemia; Hypokalaemia; Off Label Use; Product Use In Unapproved Indication; Renal Failure	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, 1x/Day		Not Reported
	Tavanic			S	Intravenous (not otherwise specified)	250 Mg, 2x/Day		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	1000 Mg, Daily		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	2 G, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17958394	EXPEDITED (15-DAY)		HO	NVSC2020ES178459		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Novartis
	Azithromycin			S				Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Dexamethasone			S				Not Reported
	Enoxaparin			S	Subcutaneous	60 Mg, Q12h		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg Total		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17958533	EXPEDITED (15-DAY)		DE, OT	NVSC2020ES181844		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Metilprednisolona			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17958833	EXPEDITED (15-DAY)		DS, LT	NVSC2020FR183087		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Plaquenil			S	Oral	400 Mg, Qd (2-3 Cp Par Jour)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17959056	EXPEDITED (15-DAY)		HO	NVSC2020US181307		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	400 Mg, Bid		Novartis
	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	9 Mg, Qd		Not Reported
	Losartan			S	Unknown	25 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17959242	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1058537		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome; Off Label Use	Azithromycin			S		Unk, Qod		Not Reported
	Hidroxicloroquina /00072601/			S		Unk		Mylan
	Kaletra			S		Unk		Mylan
	Metilprednisolona /00049601/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17959421	EXPEDITED (15-DAY)		LT, OT	ES-MYLANLABS-2020M1058595		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Disorientation; Hyperbilirubinaemia; Liver Function Test Abnormal; Off Label Use; Urinary Retention	Lopinavir/Ritonavir			S		200/20 Cuatro Veces Al Dia		Not Reported
	Levofloxacin			S		500 Mg/12 Horas		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	800 Mg 1 Dia + 400 Mg El Resto		Mylan
	Omeprazol /00661201/			C		1/24		Mylan
	Pulmicort			C		2 Puff Cada 8 Horas		Mylan
	Ventolin /00139501/			C		Unk		Mylan
	Urbason /00049601/			C		40 Mg Primero Cada 8 Horas, A Los 5 Dias Cada 12		Mylan
	Clexane			C		40/24 Horas		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960151	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-018151			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue;	Diclofenac Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961774	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3462437-00		74 YR	Male	ESP

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

Cardio-Respiratory Arrest; Covid-19; Off Label Use	Kaletra		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Paracetamol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961969	NON-EXPEDITED		OT	US-AMGEN-USASP2020102384		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy	Otezla			S	Oral	30 Milligram, Bid		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	18267263	DIRECT					70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Product Use In Unapproved Indication; Product Use Issue; Therapy Non-Responder; Transfusion	Convalescent Plasma			S		Other Route:Iv	1 DAY	Not Reported
	Lopinavir-Ritonavir			S	Oral	Other Dose:400/100 Mg;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	18267436	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lopinavir-Ritonavir			S		Other Dose:400/100 Mg;		Not Reported
	Hydroxychloroquine			S				Not Reported
	Convalescent Plasma			S	Intravenous (not otherwise specified)			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	12774372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076813		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5.0 Milligram		Not Reported
	Fosamax			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported
	Fosavance			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

	Methotrexate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	12957719	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-097111		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fatigue; Gastrointestinal Disorder; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Bid		Not Reported
	Arava			S	Unknown	1 Df, Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Methotrexate			C	Unknown	20 Milligram		Not Reported
	Sulfasalazine			C	Unknown	500 Milligram		Not Reported
	Sulfasalazine			C	Unknown	1000 Milligram		Not Reported
	Sulfasalazine			C	Unknown	1 Gram		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	13168077	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005387			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug	Orencia			S	Unknown			Bristol Myers Squibb

Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Leflunomide		S	Unknown	Unk, Qd	Not Reported
	Methotrexate		S	Unknown	20 Mg, Qwk, Cyclical	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown	400 Mg, Qd	Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	15498701	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-092561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q2wk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Methylprednisolone			S	Unknown	80 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, Q8wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Rituxan	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	15627967	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558814-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Xeljanz	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	15932948	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2655966-00		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Synovitis; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Not Reported
	Triamcinolone	S	Intra-articular	Not Reported
	Triamcinolone	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Kineret	S		Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported

	Apo-Prednisone			S	Oral					Not Reported
	Apo-Prednisone			S	Oral					Not Reported
	Vaccinia Immune Globulin			S	Unknown					Not Reported
	Immunoglobulin G Human			S	Intravenous (not otherwise specified)					Not Reported
	Folic Acid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16347535	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027959		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Red Blood Cell Sedimentation Rate Abnormal; Sleep Disorder; Spinal Operation; Spinal Stenosis	Tramadol+Paracetamol			S	Oral	Unk		Aurobindo
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Once A Day		Not Reported
	Actonel			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

Methylprednisolone	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Premarin	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Vagifem	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Vagifem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16388794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-051033		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hcl / Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported

Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Apo Prednison	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16423706	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-19K-028-2817334-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Contraindicated Product Administered; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16451258	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822497-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported

Sedimentation Rate Abnormal; Treatment Failure	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Usp		Not Reported
	Kineret	S	Subcutaneous	100 Mg Per Syringe		Not Reported
	Anakinra	S	Unknown			Not Reported
	Desoximetasone	C				Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Azathioprine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16539128	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-213078		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercalcaemia; Lymphoproliferative Disorder; Off Label Use	Methotrexate			S	Unknown	15 Milligram, Weekly		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Mycophenolate			S	Unknown	1000 Milligram, Bid		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16669953	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-073641			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported
	Infliximab			S				Not Reported
	Kineret			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Infliximab			S				Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16721389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	567 Milligram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	16749699	EXPEDITED (15-DAY)		OT	PHHY2019DE192163			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Sildenafil			S	Unknown	60 Mg, Qd		Not Reported
	Omeprazole			S	Oral	2 Df, Qd 1 Dosage Form, Bid (1-0-1)		Novartis
	Omeprazole			S	Oral	40 Mg, Qd (20 Mg, Bid)		Novartis
	Ramipril			S	Oral	5 Mg, Qd		Not Reported
	Ramipril			S	Oral	2 Df, Qd (1 Dosage Form, Bid)		Not Reported
	Apixaban			S	Unknown	5 Mg, Qd (2.5 Mg, Bid)		Not Reported
	Apixaban			S	Unknown	2 Df, Qd		Not Reported
	Pregabalin			S	Unknown	3 Df, Qd (1 Dosage Form)		Not Reported

	Pregabalin	S	Unknown	300 Mg, Qd (100 Milligram, Tid)	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
	Ambrisentan	S	Unknown	1 Df, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Roactemra	S	Unknown	162 Mg, Qw	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Quensyl	S	Unknown	80 Mg, Bid (40 Mg, Bid)	Not Reported
	Quensyl	S	Unknown	40 Mg, Qd (20 Mg, Bid)	Not Reported
	Volibris	S	Oral	30 Mg, Qd	Not Reported
	Volibris	S	Oral	1 Df, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Lyrica	S	Unknown	300 Mg, Qd (100 Mg, Tid)	Not Reported
	Eliquis	C	Unknown	2 Df, Qd 1 Dosage Form, Bid (1-0-1)	Not Reported
	Eliquis	C	Unknown	2.5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17260884	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA006562			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Prednisone	C		5 Mg, Qd	Not Reported
	Prednisone	C		10 Mg	Not Reported
	Remicade	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17565635	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022535		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Orencia			S		200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S		200 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Unk		Not Reported
	Prednisone			S	Unknown	20 Nanogram		Not Reported
	Rituximab			S	Intravenous drip	2 Gram		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Unk		Not Reported
	Apo-Prednisone			S	Unknown	20 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	200 Milligram		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17651130	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029423		74 YR	Female	CAN

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

Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Orencia	S	Unknown		Bristol Myers Squibb
	Acetaminophen	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
	Apo-Ramipril	S	Unknown	Unk, Qd	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Levothyroxine	S	Unknown	Unk, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1 Every 1 Days	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Codeine	S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	2 Every 1 Days	Not Reported
	Enbrel	S	Unknown		Not Reported
	Prednisone	S	Unknown	7 Milligram, 1 Every 1 Days	Not Reported
	Ramipril	S	Unknown	1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
	Acetaminophen, Caffeine, Dihydrocodeine Bitartrate	C	Unknown		Not Reported
	Acetaminophen;Codeine	C	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17687059	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032291		43 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Musculoskeletal Discomfort; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Orencia	S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Sunconjunctival	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported

	Prednisone		S	Unknown	1 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17710093	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201812-004113			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Toxicity To Various Agents	Hydroxychloroquine			S	Transplacental	Unk		Concordia
	Hydroxychloroquine			S	Transplacental	Unk		Concordia
	Prednisone			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17798669	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1047777		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Unknown	No Especificada		Not Reported
	Propofol			S	Unknown	Unk		Mylan
	Propofol			S				Mylan
	Dolquine			S	Oral	Un Comprimido Desayuno Y Cena		Mylan
	Midazolam			S	Unknown	Unk		Mylan
	Midazolam			S				Mylan
	Kaletra			S	Oral	Unk		Mylan
	Ceftriaxona /00672201/			S	Unknown	No Especificada		Mylan
	Manidon Hta			C		Unk		Mylan

Rilast	C	Unk		Mylan
Omnic Ocas	C	Unk		Mylan
Simvastatina	C	Unk		Mylan
Kalpress	C	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17855878	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1053459		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash; Rash Morbilliform	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Roactemra			S		1 Dosage Form, Qd		Mylan
	Clexane			S	Subcutaneous	8000 Kilo-International Unit, Qd		Mylan
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan
	Fidato			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd		Mylan
	Kaletra			S	Oral	4 Dosage Form, Qd		Mylan
	Urbason /00049602/			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17856792	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043533			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17875556	EXPEDITED (15-DAY)		CA, HO	NVSC2020ES159718		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acquired Porphyria; Anxiety; Chromaturia; Hepatic Function Abnormal; Ileus Paralytic; Malaise; Porphyria Acute; Vomiting	Hydroxychloroquine			S	Unknown	Dose Of 400 Mg/Day		Novartis
	Levofloxacin			C	Unknown	500 Mg, Qd		Not Reported
	Prednisone			C	Unknown	1 Mg/Kg, Qd		Not Reported
	Prednisone			C	Unknown	Last Dose After Tapering		Not Reported
	Ceftriaxone			C	Unknown	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17878158	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-202005006090			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocarditis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd For 10 Days		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17878710	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA142034			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Topicort			S	Cutaneous			Sanofi
	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported

Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Pseudoephedrine Hydrochloride	S	Unknown		Sanofi
	Hydrocortisone Acetate	S	Subcutaneous		Sanofi
	Hydrocortisone	S	Oral		Sanofi
	Folic Acid	S	Oral	5 Mg	Not Reported
	Folic Acid	S		Unk	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cetirizine Hydrochloride	S		20 Mg	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S		10 Mg	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Plaquenil	S	Oral	400 Mg, Qd	Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	S	Oral	1 Df, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Qd	Not Reported
	Methotrexate	S		20 Mg Qd	Not Reported
	Prednisone	S			Not Reported
	Arava	S	Oral	20 Mg	Sanofi
	Sulfasalazine	S	Subcutaneous	1 G, Qd	Not Reported
	Sulfasalazine	S		500 Mg	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Alendronate Sodium	S			Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Sarilumab	S			Sanofi
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Apo-Prednisone	S			Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Golimumab	S			Not Reported

Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Paracetamol	S				Not Reported
Phthalylsulfathiazole	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Stelara	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	S		5 Mg, Qd		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfathalidine	S	Unknown			Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid		Not Reported
Acetaminophen	S				Not Reported
Reactine [Cetirizine Hydrochloride]	S				Not Reported
Salazopyrin	C	Oral	2000 Mg, Qd		Not Reported
Salazopyrin	C				Not Reported
Atasol [Paracetamol]	C				Not Reported
Tofacitinib Citrate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17885722	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1055417		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Off Label Use	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	400 Mg, Qd		Mylan
	Plaquenil /00072603/			S	Oral	600 Mg, Qd		Mylan
	Plaquenil /00072603/			S		Unk		Mylan

	Plaquenil /00072603/	S		Unk	Mylan
	Indapamide	C		Unk	Mylan
	Kcl	C		Unk	Mylan
	Amlodipine	C		Unk	Mylan
	Lovenox	C		Unk	Mylan
	Cefotaxime	C		Unk	Mylan
	Spiramycin	C	Oral	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17889836	EXPEDITED (15-DAY)		DE, HO, OT	IT-MYLANLABS-2020M1056476		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukocytosis; Pyrexia; Respiratory Distress; Sepsis	Clopidogrel			S	Oral	300 Milligram		Not Reported
	Clopidogrel			S	Oral	75 Milligram, Qd		Not Reported
	Acetylsalicylic Acid			S	Intravenous (not otherwise specified)	250 Milligram, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	75 Milligram, Qd		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	2.5 Milligram, Qd		Mylan
	Tirofiban /01383302/			S	Intravenous bolus	25 Microgram/Kilogram		Mylan
	Tirofiban /01383302/			S	Intravenous (not otherwise specified)	0.15 ?G/Kgbody Per Minute For 48 Hours;		Mylan
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Mylan
	Methylprednisolone			S	Unknown	1 Milligram/Kilogram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17897497	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044950		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia;	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb

Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70.0 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported

Methotrexate	S	Subcutaneous	10 Milligram, Qwk		Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, Qwk		Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk		Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk		Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	1000 Milligram, 2 Every 1 Day		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Tocilizumab	S	Unknown	360 Milligram		Not Reported
Tocilizumab	S	Unknown	380 Milligram		Not Reported
Ciclosporin	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Alendronic Acid	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17901396	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200614408		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Gold	S		Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Methotrexate	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17903957	NON-EXPEDITED			US-ADVANZ PHARMA-202006006186			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17927429	EXPEDITED (15-DAY)		DE	NVSC2020ES172807		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Sudden Death	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, Q6h		Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, Q8h		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Dolquine			S	Oral	400 Mg, Q12h		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	Unk		Not Reported
	Cefotaxima			C	Intravenous drip	4 G, Q12h		Not Reported
	Ipratropio Bromuro			C	Respiratory (inhalation)	20 Ug, Q6h		Not Reported

Midazolam	C	Intravenous drip	100 Mg, Qd		Not Reported
Tocilizumab	C	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17936835	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020239328		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Use Error; Hand Deformity; Peripheral Coldness; Psoriasis; Renal Failure; Syncope	Enbrel Mini With Autotouch			S	Unknown	Unk		Unknown
	Enbrel Mini With Autotouch			S	Unknown	Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17944082	EXPEDITED (15-DAY)		OT	ES-EMD SERONO-E2B_90078167		69 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia	Interferon Beta-1a			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Levofloxacino (2791a)			S				Not Reported
	Kaletra			S	Oral			Not Reported
	Azitromicina (7019a)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17948295	EXPEDITED (15-DAY)		OT	NVSC2020BE173408		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Interaction;	Olanzapine			S	Oral	1 Df, Qd(1/2 Tablet		Novartis

Electrocardiogram Qt Prolonged; Off Label Use				2x/Day, Treatment Was Suspended For 2 Days 11 Apr And 12 Apr And Then Resumed)	
	Trazodone Eg	S	Oral	1 Df, Qd(1/4 Tablet In The Morning And At Noon And 1/2 Tabletin The Evening, Interruption Of Treatme	Not Reported
	Zyprexa	S	Oral	1 Df Qd, 1/2 Tablet 2x/Day, Treatment Was Suspended For 2 Days 11/04 And 12/04 And Then Resumed	Not Reported
	Plaquenil	S	Oral	400 Mg (Day 1: 400mg 2x/Dday 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg08/04 To 10/04 Received A Tota	Not Reported
	Plaquenil	S	Oral	400 Mg (Day 1: 400mg 2x/Dday 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg08/04 To 10/04 Received A Tota	Not Reported
	Algostase Mono	C	Unknown	1 Df, Tid	Not Reported
	Algostase Mono	C	Unknown	3 Df, Qd	Not Reported
	Contramal	C	Unknown	1 Df, Prn	Not Reported
	Pradaxa	C	Unknown	Unk	Not Reported
	Movicol	C	Oral	1 Df, Qd , 1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The Evening	Not Reported
	Uni Diamicron	C	Unknown	60 Mg, Bid	Not Reported
	L Thyroxin	C	Unknown	150 Ug, Qd	Not Reported
	L Thyroxin	C	Unknown	1 Df, Qd	Not Reported
	Metformin	C	Unknown	500 Mg, Q12h	Not Reported
	Metformin	C	Unknown	2 Df, Qd	Not Reported

Magnetop	C	Oral	450 Mg, Qd		Not Reported
Clexane	C	Unknown	Qd		Not Reported
Perindopril	C	Unknown	1 Df, Qd		Not Reported
Perindopril	C	Unknown	1 Df, Qd		Not Reported
Kalium	C	Oral	600 Mg		Not Reported
Prolopa	C	Unknown	0.5 Df, Qd		Not Reported
Potassium	C	Unknown	Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17958918	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17959166	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009624			Female	CAN

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

Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Tylenol [Paracetamol]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17961228	NON-EXPEDITED			US-ADVANZ PHARMA-202006006551			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Residue Present	Hydroxychloroquine			S		Tablet (Takes This Medication About 2 Hrs After Eating)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17961265	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1795005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17961414	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1794976		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride\Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride\Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown	10 Milligram Daily;	Not Reported
	Topicort	S	Cutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17961420	NON-EXPEDITED			US-ADVANZ PHARMA-202006006556			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17961422	NON-EXPEDITED			US-ADVANZ PHARMA-202006006658			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Onychomadesis	Hydroxychloroquine			S		Unk		Concordia
	Leflunomide			S				Not Reported

Sulfoacetate [Unspecified]	S				Not Reported
Prednisone	S		3.5 Mg, Qd (1 Mg Night And 2.5 Mg In Morning)		Not Reported
Xeljanz	S	Oral	5 Mg, Bid (1 Tablet In The Morning And 1 Tablet By Mouth At Night)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17961950	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202006006708			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Dry Eye; Dry Throat; Ear Pain; Fatigue; Feeling Abnormal; Gastric Disorder; Gastrointestinal Disorder; General Physical Condition Abnormal; Hypersensitivity; Immunodeficiency; Osteoarthritis; Psoriatic Arthropathy; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Thirst; Vertigo	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Rinvoq			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962376	EXPEDITED (15-DAY)		OT	CA-ACCORD-187388		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea; Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Methotrexate			S	Unknown	Not Specified		Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962398	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2753750-00		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962755	EXPEDITED (15-DAY)		HO	CA-ACCORD-187053		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Asthenia; Chest Discomfort; Drug Ineffective; Dyspnoea; Headache; Heart Rate Increased; Hyperhidrosis; Left Ventricular Dilatation; Myocarditis; Nausea; Nephritis; Pleuritic Pain; Systemic Lupus Erythematosus; Treatment Failure; Vasculitis	Mycophenolic Acid			S	Oral	2 Every 1 Days		Accord
	Hydroxychloroquine			S	Unknown	1 Every 24 Hours		Not Reported
	Azathioprine			S	Unknown	1 Every 24 Hours		Not Reported
	Acetylsalicylic Acid			C	Unknown	1 Every 24 Hours		Not Reported
	Colchicine			C	Unknown	1 Every 24 Hours		Not Reported
	Naproxen			C	Unknown	2 Every 1 Days		Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963266	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202006006753			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Colitis;	Hydroxychloroquine			S		Unk		Concordia

Cytomegalovirus Gastrointestinal Infection	Prednisone		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963338	NON-EXPEDITED			US-ADVANZ PHARMA-202006006531			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Malaise; Product Substitution Issue	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963583	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043525			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Arava			S	Oral	10 Mg,Qod		Sanofi
	Arava			S	Oral	200 Mg,Biw		Sanofi
	Arava			S	Oral	10 Mg,Qod		Sanofi
	Arava			S	Oral	10 Mg,Biw		Sanofi
	Arava			S	Oral	10 Mg,Qd		Sanofi
	Arava			S	Oral	10 Mg,Tiw		Sanofi
	Arava			S	Unknown	10 Mg		Sanofi
	Plaquenil			S	Oral	200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Intramuscular	Unk Unk,Unk		Not Reported
	Methotrexate			S	Intramuscular	125 Mg		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg,Qw		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg,Qd		Not Reported
	Methotrexate			S		40 Mg		Not Reported
	Methotrexate			S		1 Every 2 Year		Not Reported
	Methotrexate			S	Other	125 Mg		Not Reported

Enbrel	S	Subcutaneous	50 Mg,Qw		Not Reported
Enbrel	S		50 Mg		Not Reported
Humira	S	Subcutaneous	40 Mg,Qcy		Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Qcy		Not Reported
Methotrexate Sodium	S		40 Mg		Not Reported
Methotrexate Sodium	S	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17964240	EXPEDITED (15-DAY)		OT	CA-ACCORD-187494			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspnoea; Hypertension; Neoplasm Malignant	Methotrexate			S		1 Every 1 Weeks		Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17964255	EXPEDITED (15-DAY)		OT	CA-ACCORD-187530			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled		Not Reported

				Syringe		
	Diclofenac	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Fosamax	S	Oral			Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Reactine [Cetirizine]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	Subcutaneous Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17964653	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609664		40 YR	Male	CAN

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

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17964891	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2020M1059608		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebral Venous Thrombosis; Disseminated Intravascular Coagulation; Drug Interaction; Dyspnoea; Headache; Hemiparesis; Mental Disorder; Off Label Use; Product Use In Unapproved Indication; Pulmonary Artery Thrombosis; Vena Cava Thrombosis	Azithromycin			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Oxygen			S	Respiratory (inhalation)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17964964	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2768008-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17964965	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1059467		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Ceftriaxone			S		Unk		Mylan
	Tocilizumab			S	Intravenous bolus	3 Bolus		Mylan
	Methylprednisolone			S	Intravenous bolus	Unk		Mylan
	Methylprednisolone			S		Unk Unk, Qd, (+/- 1 Mg/Kg Day)		Mylan
	Interferon Beta-1b			S	Subcutaneous	Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17965036	EXPEDITED (15-DAY)		OT	NVSC2020ES181812		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h (400 Mg Dia)		Novartis
	Azithromycin			S	Oral	500 Mg, Q24h (500 Mg Dia)		Not Reported
	Enoxaparina			S	Subcutaneous	60 Mg, Q24h		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Q24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17965334	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-018148		43 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Cortisone	S	Unknown	Not Reported
	Cortisone	S	Oral	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17965407	EXPEDITED (15-DAY)		OT	NVSC2020ES179751		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia	Azithromycin			S	Unknown	Unk ((No Especificada))		Novartis
	Hydroxychloroquine			S	Oral	1 Df, Q12h (400 Mg C/12 Horas Seguido De 200 Mg C/12 Horas)		Not Reported
	Hydroxychloroquine			S				Not Reported
	Ceftriaxona			S	Unknown	Unk (No Especificada)		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Df, Q12h (400 Mg C/12 Horas 200 Mg/ 50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimidos (B		Not Reported
	Lopinavir + Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17965408	EXPEDITED (15-DAY)		OT	NVSC2020FR179839		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Amoxicillin Trihydrate			S	Oral	3 G		Novartis
	Acide Clavulanique			S	Oral	600 Mg		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17965467	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-	Orencia			S	Unknown			Bristol Myers Squibb

Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Orencia	S				Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Actemra	S				Not Reported
	Enbrel	S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira	S				Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Milligram, Qwk		Not Reported
	Infliximab	S				Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	420 Milligram		Not Reported
	Rituximab	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17965499	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050223			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17966166	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050247		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17966179	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050179		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Nausea; Obesity; Septic Shock; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17966465	EXPEDITED (15-DAY)		OT	NVSC2020ES183382		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis
	Furosemide			S	Oral	20 Mg, Q24h		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk Every		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Unk Every		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	12767211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015691		65 YR	Male	CAN

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

Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Onychoclasis; Synovitis; Tooth Loss	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Enbrel	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	10 Milligram, Bid	Not Reported
	Xeljanz	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	C	Oral	10 Milligram, Qd	Not Reported
	Desoximetasone	C	Oral	5 Milligram 2 Every 1 Day	Not Reported
	Zostavax	C	Subcutaneous	Unk	Not Reported
	Cortisone	C	Oral	10 Milligram, Qd	Not Reported
	Diclofenac	C	Subcutaneous	100 Milligram, Qd	Not Reported
	Voltaren Acti	C	Unknown	100 Milligram, Qd	Not Reported
	Cortisone Acetate	C	Subcutaneous		Not Reported
	Desoximetasone	C	Subcutaneous		Not Reported

Diclofenac	C	Oral	50 Milligram, Bid		Not Reported
Diclofenac	C	Oral	100 Milligram, Qd		Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	12916483	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091700		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	0.5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	25 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	5 Milligram	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported

Sulfasalazine	S	Oral	1 Gram (2 Every 1 Day)	Not Reported
Winpred	S	Oral	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram (2 Every 1 Days)	Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Topicort Lp	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	13165412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005507		62 YR	Male	CAN

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

Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	150 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	15 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	13982243	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083368		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Methotrexate			S				Not Reported

Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Infliximab	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	50 Milligram	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S			Not Reported
	Ramipril	S	Unknown		Not Reported
	Methadone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unk, Qwk	Not Reported
	Ergocalciferol	C		Unk, Qd	Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
	Estradiol	C	Unknown	0.6 Percent, Tid	Not Reported
	Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
	Estrogel	C		Unk, Qd	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Milligram, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported
	Gravol Ginger Nighttime	C	Oral	500 Milligram	Not Reported
	Tofacitinib Citrate	C	Oral	5 Mg, Bid	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Baclofen	C	Unknown	10 Milligram, Bid	Not Reported
	Gravol	C	Unknown	Unk Milligram	Not Reported
	Levaquin	C		50 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

	Calcium			C	Unknown	500 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	14900180	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-041965		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Miliaria; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Morphine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Celebrex			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	1 Mg (Bedtime) (1 Every One Hour)		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	200 Milligram, Bid		Not Reported
	Gold			S	Unknown			Not Reported
	Citalopram			S	Unknown	10 Mg, Qd		Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	40 Mg, Bid		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	40 Milligram, 2 Every 1 Week		Not Reported
	Morphine			C	Unknown			Not Reported

	Celebrex		C	Unknown	200 Milligram, Bid	Not Reported
	Lorazepam		C	Unknown	1 Milligram, Qd	Not Reported
	Methotrexate		C	Unknown	25 Milligram, Qwk	Not Reported
	Citalopram		C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	15337218	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-079001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	500 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown	35 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported

	Sulfasalazine		S	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported
	Codeine		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Certolizumab Pegol		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	15622680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557508-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	15622706	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555912-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

Apo-Cyclosporine	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Azathioprine	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Gold	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ciclosporin	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Imuran	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Azathioprine Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	15731126	EXPEDITED (15-DAY)		OT	CA-SA-2018SA339535			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S		Unk Unk, Unk		Sanofi
	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Diphenhydramine Hydrochloride			S		Unk		Sanofi

Celecoxib	S	Oral	Unk, Unk		Not Reported
Levofloxacin	S		Unk, Unk		Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
Methotrexate	S		Unk Unk, Unk		Not Reported
Azithromycin	S		250 Mg, Qd		Not Reported
Cimzia	S	Subcutaneous	Unk, Unk		Not Reported
Enbrel	S		Unk, Unk		Not Reported
Humira	S	Subcutaneous	Unk, Unk		Not Reported
Imuran [Azathioprine Sodium]	S		Unk		Not Reported
Simponi	S	Subcutaneous	Unk, Unk		Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid		Not Reported
Ezetrol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	15978440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk, Q2wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Unknown		Not Reported
Advil [Ibuprofen]	C	Unknown		Not Reported
Prednisone	C	Oral	6 Milligram, Qwk	Not Reported
Prednisone	C	Oral	10 Milligram, Qd	Not Reported
Tylenol	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Mefenamic Acid	C	Unknown		Not Reported
Dequalinium Chloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	16403442	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2808944-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	16431043	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2819807-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	16694385	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Bid		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Sulfasalazine			C	Unknown	Unk, Bid		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	16820266	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-19K-028-2927400-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Triamcinolone			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Hydroxychloroquine Sulfate Tablets, Usp		Not Reported
	Kineret			S	Subcutaneous	Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Infliximab	S				Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Naproxen	S	Unknown			Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S				Not Reported
Gammagard	S	Intravenous (not otherwise specified)			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Suspension Intraarticular		Not Reported
Triamcinolone Acetonide	S				Not Reported
Triamcinolone Acetonide	S				Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Gamastan	S	Intravenous (not otherwise specified)	Solution Intramuscular		Not Reported
Anakinra	S	Subcutaneous			Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Suspension Intraarticular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17005829	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103681		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Methotrexate	S	Oral	25 Milligram, Qd		Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17629123	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2020014089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S		162.0 Milligram		Not Reported
	Azathioprine			C		162 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17690857	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032312		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Rituxan	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Alendronate Sodium	C	Unknown	70 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17836250	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-026603		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Intentional Product Use Issue; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Two Times A Day		Not Reported

	Ceftriaxone		S	Intravenous (not otherwise specified)	1 Gram, Once A Day	Not Reported
	Roactemra		S	Intravenous (not otherwise specified)	400 Milligram, Once A Day	Not Reported
	Enoxaparin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17912767	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020230100		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Sarilumab			S	Intravenous (not otherwise specified)	400 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Indapamide			C		Unk		Not Reported
	Kcl			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Cefotaxime			C		Unk		Not Reported
	Spiramycin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17917173	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020230573		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Amlodipine			S	Oral	10 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Every 8 Hours		Not Reported
	Sarilumab			S	Intravenous (not	400 Mg, 1x/Day		Not Reported

			otherwise specified)		
	Sarilumab	S			Not Reported
	Hydrochlorothiazide	S		Unk	Not Reported
	Enoxaparin	S	Intramuscular	4000 Iu, 1x/Day	Not Reported
	Spironolactone	C		Unk	Not Reported
	Salbutamol	C		Unk	Not Reported
	Esidrex	C		Unk	Not Reported
	Levothyrox	C		Unk	Not Reported
	Tanganil	C		Unk	Not Reported
	Euthyrox	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17954566	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02577		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, 400 Milligram, Loading Dose For 2 Doses And Then 200 Mg Twice Daily For A Total Of 5		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid, 400 Milligram, Loading Dose For 2 Doses And Then 200 Mg Twice Daily For A Total		Lupin
	Betamethasone			S	Intramuscular	12 Milligram, Qd, 12 Mg Once Daily For 2 Doses		Lupin
	Prednisone			S	Oral	80 Milligram, Bid		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17959265	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3457009-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17965226	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251892		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination	Azithromycin			S	Oral	Unk		Sun
	Hidroxicloroquina (2143a)			S	Oral	Unk		Not Reported
	Interferon Beta-1b (2305od)			S	Unknown	250 Milligram, 1dose/48hour		Not Reported
	Enoxaparina (2482a)			C	Unknown	Unk		Not Reported
	Kaletra			C	Unknown	Unk		Not Reported
	Genvoya			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17965811	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013928		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Venlafaxine			S	Unknown	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Every Week		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Every Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Every Month		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966085	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048317			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark
	Arava			S	Oral	20 Milligram, 1 Every 1 Months		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Months		Not Reported
	Celebrex			S	Other	Unk (Route: Occlusive Dressing Technique)		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qw		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Od		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw (1 Every 1 Weeks)		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Weeks (Formulation: Solution Intramuscular)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 3 Weeks		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Od		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	Unk (Formulation: Solution Intravenous)		Not Reported
	Biotin			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ferrous Fumarate			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Lomotil /00034001/			C	Unknown	Unk		Not Reported
	Loperamide			C	Unknown	Unk		Not Reported
	Nasonex			C	Unknown	Unk		Not Reported

	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Pyridoxine	C	Unknown	Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin A /00056001/	C	Unknown	Unk	Not Reported
	Vitamin B1 /00056101/	C	Unknown	Unk	Not Reported
	Vitamin C /00008001/	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966127	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050266			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown			Not Reported
Fosamax	S	Unknown			Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966144	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased;	Orencia			S	Unknown			Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Etanercept			S	Subcutaneous	15 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Milligram/Sq. Meter		Not Reported

Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Humira		S	Subcutaneous	Solution Subcutaneous 40milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966505	NON-EXPEDITED			US-ADVANZ PHARMA-202006006659			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966506	NON-EXPEDITED			US-ADVANZ PHARMA-202006006536			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Concordia
	Prednisone			C		Unk, 2 Rounds		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966508	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201705-003053			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	300 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	300 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	Every 24 Hours, Tablet		Concordia
	Hydroxychloroquine			S	Oral	Tablet, Daily Dose : Unknown		Concordia
	Hydroxychloroquine			S	Oral	Tablet, 300 Mg, Freq: Unk		Concordia

Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis				Qcy	
	Hydroxychloroquine	S	Unknown	Daily Dose: Unknown	Concordia
	Hydroxychloroquine	S	Unknown	300 Mg, Qd, Apo-Hydroxyquine	Concordia
	Leflunomide	S	Oral	20 Mg, Qcy	Not Reported
	Leflunomide	S	Oral	20 Mg, Qh	Not Reported
	Actemra	S	Unknown	Daily Dose: Unknown	Not Reported
	Actemra	S	Subcutaneous	Daily Dose: Unknown	Not Reported
	Enbrel	S	Unknown	Daily Dose : Unknown	Not Reported
	Enbrel	S	Subcutaneous	Daily Dose: Unknown	Not Reported
	Humira	S	Subcutaneous	Daily Dose: Unknown, Solution	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Mg, Weekly	Not Reported
	Risedronate Sodium	S	Oral	35 Mg, Weekly	Not Reported
	Risedronate Sodium	S	Unknown	35 Mg, Weekly	Not Reported
	Risedronate Sodium	S	Unknown	Tablet, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Daily Dose: 1 G,Qcy	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S			Not Reported
	Apo Risedronate	S	Unknown	35 Mg, Weekly	Not Reported
	Actonel	S	Unknown	35 Mg, Weekly	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Freq: Unk X 1 Cyclical	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Freq: Unk X 1 Hour	Not Reported
	Arava	S	Oral	Daily Dose: Unknown	Not Reported

Arava	S	Oral	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk, Single		Not Reported
Sodium Aurothiomalate	S	Unknown	Daily Dose: Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Daily Dose: Unknown		Not Reported
Risedronic Acid	S	Unknown	35 Mg, Weekly		Not Reported
Simponi	S	Unknown	Daily Dose: Unknown		Not Reported
Xeljanz	S	Oral	10 Mg, Qd		Not Reported
Hydroxychloroquine	C				Not Reported
Risedronate	C		Unk		Not Reported
Hydroxychloroquine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966512	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Endocervical	1 Dosage Form:25 (Unit Not Specified), Qwk		Not Reported
	Methotrexate			S		20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/ Power For Solution		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous	Solution		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram		Not Reported
	Meloxicam	C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk		Not Reported
	Synthroid	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966530	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050200			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966533	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050313		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram, Qd		Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Biotin			C	Unknown			Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Ferrous Fumarate			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported

Pantoprazole Magnesium	C	Unknown	Not Reported
Perphenazine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Pyridoxine	C	Unknown	Not Reported
Retinol Palmitate	C	Unknown	Not Reported
Riboflavin	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported
Thiamine Hcl	C	Unknown	Not Reported
Thiamine Mononitrate	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Vitamin A [Retinol]	C	Unknown	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966544	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050187		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Orencia			S	Unknown	250 Milligram		Bristol Myers Squibb
	Prednisone			S	Oral	5.0 Milligram, 2 Every 1 Weeks		Not Reported
	Sulfasalazine			S	Unknown	250 Milligram, 1 Every 1 Days		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	3.0 Milligram, 1 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not	280 Milligram		Not Reported

			otherwise specified)		
	Anakinra	S	Unknown	50 Milligram, 1 Every1 Days	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966546	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050336			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966599	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17966642	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202006006705			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthritis Reactive; Drug Ineffective; Drug Ineffective; Fatigue; Finger Deformity; Joint Effusion; Joint Noise; Musculoskeletal Stiffness; Osteoarthritis; Pain; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased;	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Rayos			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported

Sacroiliitis; Spinal Osteoarthritis; Swelling; Synovitis; Vitamin D Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967025	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051349		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown	25 Milligram		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Sunconjunctival	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral	1 Gram 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967046	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967209	EXPEDITED (15-DAY)		OT	NVSC2020IT180786		55 YR	Female	ITA

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

Urticaria	Azithromycin	S	Oral	500 Mg, Qd		Novartis
	Plaquenil	S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967212	EXPEDITED (15-DAY)		HO	NVSC2020IT180463		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Df, Qd		Novartis
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967344	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole		S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride		S	Unknown	Not Reported
	Reactine [Cetirizine]		S	Unknown	Not Reported
	Remicade		S	Intravenous bolus	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967431	EXPEDITED (15-DAY)		OT	CH-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-251878		62 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication	Lopinavir/Ritonavir			S	Unknown	Unk, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Bid		Sun
	Cefepime			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967450	EXPEDITED (15-DAY)		OT	CA-ACCORD-187666		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S				Not Reported
	Aurothioglucose			S	Intramuscular			Not Reported
	Leflunomide			S	Oral			Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Accord
	Azathioprine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Accord
	Hydroxychloroquine	S	Unknown	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967790	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050206			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Prednison			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	50 Milligram		Not Reported

Pain; Pemphigus; Pericarditis; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Diclofenac Diethylamine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	0.5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Salazopyrine	S	Oral	1 Gram 2 Every 1 Day	Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelera	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported

	Sulfasalazine	S	Oral	500 Milligram		Not Reported
	Tocilizumab	S	Subcutaneous			Not Reported
	Topicort [Hydrocortisone Acetate]	S	Oral	Unk		Not Reported
	Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk		Not Reported
	Winpred	S	Oral			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Tofacitinib Citrate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967877	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052214		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968016	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202006006816			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection Susceptibility Increased	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968252	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968254	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795029		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Sunconjunctival			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	2 Gram Daily;		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

					Phthalylsulfathiazole		S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
					Reactine [Cetirizine]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968255	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795020			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968260	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1794994		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Diclofenac			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral	20 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfathalidine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfathalidine	S	Oral		Not Reported
Tofacitinib	S	Unknown	10 Milligram Daily;	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;	Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968345	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795456		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue;	Methotrexate			S	Unknown			Barr
	Venlafaxine			S	Unknown	37.5 Milligram Daily;		Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Rheumatoid Arthritis				otherwise specified)		
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Folic Acid		C	Unknown	12.5 Milligram Daily;	Not Reported
	M-Eslon		C	Unknown	20 Milligram Daily;	Not Reported
	Morphine		C			Not Reported
	Morphine Sulfate		C			Not Reported
	Statex		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968386	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050235		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968601	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy;	Diclofenac			S	Unknown			Actavis
	Diclofenac Diethylamine			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr

Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Live Birth; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown	20 Milligram Daily;	Barr
	Methotrexate	S	Subcutaneous		Barr
	Prednisone	S	Unknown		Actavis
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo Prednison	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S			Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported

Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Subcutaneous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Salazopyrine	S	Oral	2 Gram Daily;	Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelera	S	Unknown		Not Reported
Sulfasalazine	S	Oral	1000 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Winpred	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968720	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794896		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use;	Diclofenac Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968846	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794938		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Diclofenac			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported

	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Topicort	S	Other	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
	Salazopyrin	C		Not Reported
	Tofacitinib Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968865	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1793222		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Hidroxicloroquina (2143a)			S	Oral	400 Mg W / 12 Hours Followed By 200 Mg W / 12 Hours		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; Every 24 Hours		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S	Oral	400 Mg C/ 12h. 2 Dosage Forms		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not	2 Gram		Not Reported

		otherwise specified)	
	Omeprazol (2141a)	C	Not Reported
	Deprax 100 Mg Comprimidos Recubiertos Con Pelicula Efg	C	Not Reported
	Rhinom - Rhinomer Nasal Spray	C	Not Reported
	Manidon Retard 120 Mg Comprimidos De Liberacion Prolongada	C	Not Reported
	Sintrom	C	Not Reported
	Paracetamol (12a)	C	Not Reported
	Duphalac 10 G Solucion Oral En Sobre	C	Not Reported
	Bisoprolol 2,5 Mg Comprimido	C	Not Reported
	Seretide	C	Not Reported
	Escitalopram (2858a)	C	Not Reported
	Humalog	C	Not Reported
	Furosemida (1615a)	C	Not Reported
	Alprazolam 1 Mg Comprimido	C	Not Reported
	Sinemet Plus Retard 25 Mg/100 Mg Comprimidos De Liberacion Prolongada	C	Not Reported
	Atrovent	C	Not Reported
	Noctamid 1 Mg Comprimidos	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969491	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795799		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Methotrexate			S	Unknown			Barr
	Cyclosporin A			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Oxycodone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Depo-Provera			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

	Folic Acid			S	Unknown					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Infliximab			S	Unknown					Not Reported
	Naprosyn [Naproxen]			S	Unknown					Not Reported
	Rituximab			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969492	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795813		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969522	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1059295		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Azithromycin			S	Oral	500 Mg Cada 24 Horas		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg C/12 Horas Seguido De 200 Mg C/12 Horas		Mylan
	Lopinavir And Ritonavir 200mg/50mg Tablets			S	Oral	400 Mg C/ 12h		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd		Mylan
	Omeprazol /00661201/			C		Unk		Mylan
	Deprax /00447702/			C		Unk		Mylan
	Rhinomer			C		Unk		Mylan
	Manidon			C		Unk		Mylan
	Sintrom			C		Unk		Mylan
	Paracetamol			C		Unk		Mylan
	Duphalac /00163401/			C		Unk		Mylan
	Bisoprolol			C		Unk		Mylan
	Seretide			C		Unk		Mylan
	Escitalopram			C		Unk		Mylan
	Humalog			C		Unk		Mylan
	Furosemida /00032601/			C		Unk		Mylan
	Alprazolam			C		Unk		Mylan
	Sinemet Plus			C		Unk		Mylan
	Atrovent			C		Unk		Mylan
	Noctamid			C		Unk		Mylan

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969625	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Topicort (Desoximetasone)	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969661	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Diclofenac			S	Oral			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Meloxicam			S	Oral	7.5 Milligram Daily;		Not Reported
	Pantoprazole			S	Oral	1 Dosage Forms Daily;		Teva
	Pantoprazole			S	Unknown			Teva
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Cosentyx			S	Oral			Not Reported

	Diltiazem Hydrochloride	C	Oral	Not Reported
	Fluticasone Propionate	C	Respiratory (inhalation)	Not Reported
	Mar-Pantoprazole	C	Unknown	Not Reported
	Mometasone Furoate	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Salbutamol	C	Respiratory (inhalation)	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969685	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate Sodium			S	Intra-arterial			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969686	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969688	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral	5 Milligram		Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Simponi	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969700	EXPEDITED (15-DAY)		HO, OT	BE-IPCA LABORATORIES LIMITED-IPC-2020-BE-002046			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemolysis; Off Label Use; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Azithromycin			C	Unknown	500 Milligram		Not Reported
	Azithromycin			C	Unknown	250 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969712	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain;	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969713	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Actemra	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969714	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795030		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Diclofenac Potassium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Rituximab			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969826	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794937			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969837	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794992		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Folic Acid			S	Oral	5 Milligram		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydrocortisone			S	Oral			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	1 Dosage Forms Daily;		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Subcutaneous			Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram Daily;	Not Reported
Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Topicort	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	5 Milligram Daily;	Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969869	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048319			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Od		Not Reported

Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 3 Weeks (Formulation: Solution Intramuscular)	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Months	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qw	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Days	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram, Od	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Calcium	C	Unknown	1 Dosage Form, Od	Not Reported
	Ergocalciferol	C	Unknown	Unk, 1 Every 1 Hours	Not Reported
	Esomeprazole Magnesium	C	Unknown	40 Milligram, Bid	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram, Od	Not Reported
	Lomotil /00034001/	C	Unknown	2.5 Milligram, Od	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Od	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Gigabecquerel, 1 Every 1 Hours	Not Reported
	Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Bid	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Od	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, 1 Every 1 Hours	Not Reported
	Tylenol /00020001/	C	Oral	1000 Milligram, 1 Every 1 Hours	Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969870	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048316			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark
	Apo-Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Od		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Od		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Od		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Weeks (Solution Intramuscular)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Months		Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram, Od		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	Unk (Solution Intravenous)		Not Reported
	Biotin			C	Unknown	Unk		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ferrous Fumarate			C	Unknown	Unk		Not Reported

Loperamide	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Perphenazine	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	Unk	Not Reported
Thiamine Hcl	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969872	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048318			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Od		Not Reported
	Myochrysine			S	Intramuscular	60 Milligram, Unk		Not Reported

Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure				(Formulation: Solution Intramuscular)	
	Oxycontin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qw	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Months	Not Reported
	Orencia	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Od	Not Reported
	Aclasta	C	Unknown	Unk (Formulation: Solution Intravenous)	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Genteal /00445101/	C	Unknown	Unk	Not Reported
	Lomotil /00034001/	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969874	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048325			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood	Gabapentin			S	Oral	100 Milligram, 2 Every 1 Days		Glenmark

Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	488.0 Milligram, 1 Every 1 Month	Not Reported
	Arava	S	Oral	20 Milligram, 1 Every 1 Days	Not Reported
	Celebrex	S	Occlusive dressing technique	Unk	Not Reported
	Docosahexaenoic Acid W/Eicosapentaenoic Acid	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, 1 Every 1 Weeks	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Methotrexate	S	Unknown	1 Every 1week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 3 Weeks	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, 1 Every 1 Days	Not Reported
	Vitamin B1 /00056101/	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Fumarate	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Lomotil /00034001/	C	Unknown	Unk	Not Reported

Loperamide	C	Unknown			Not Reported
Nasonex	C	Unknown	Unk		Not Reported
Nicotinamide	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Retinol Palmitate	C	Unknown	Unk		Not Reported
Riboflavin	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Unknown	Unk		Not Reported
Thiamine Hydrochloride	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported
Vitamin A /00056001/	C	Unknown	Unk		Not Reported
Vitamin B6	C	Unknown	Unk		Not Reported
Vitamin C /00008001/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969974	EXPEDITED (15-DAY)		HO	NVSC2020ES181817		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h (400 Mg Dia)		Novartis
	Azithromycin			S	Oral	500 Mg, Q24h (500 Mg Dia)		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Q24h (2 Gr Dia)		Not Reported
	Piperacilin/Tazobactam			S	Intravenous (not otherwise specified)	1 Amp/8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969982	EXPEDITED (15-DAY)		CA, OT	NVSC2020FR180630			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Achromotrichia Congenital	Parlodel			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Hydrocorticone			S	Transplacental	Maternal Dose: 100 Mg, Qd		Not Reported
	Zithromax			S	Transplacental	Maternal Dose: 250 Mg, Qd		Not Reported
	Plaquenil			S	Transplacental	Maternal Dose: 600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970128	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052277		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970198	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020025954		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Neoplasm Malignant; Osteoarthritis; Pancytopenia	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Milligram, Once Daily (Qd)		Not Reported

	Leflunomide	S			Not Reported
	Methotrexate	S			Not Reported
	Elavil [Amitriptyline Hydrochloride]	C			Not Reported
	Furosemide	C			Not Reported
	Lansoprazole	C	30 Milligram, Once Daily (Qd)		Not Reported
	Tylenol [Paracetamol]	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970276	EXPEDITED (15-DAY)		OT	US-SA-2020SA169578			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Dry Eye; Dry Throat; Ear Pain; Fatigue; Feeling Abnormal; Gastric Disorder; Gastrointestinal Disorder; General Physical Condition Abnormal; Hypersensitivity; Immunodeficiency; Osteoarthritis; Psoriatic Arthropathy; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Thirst; Vertigo	Hydroxychloroquine			S		Unk		Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Rinvoq			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970839	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb

Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S			Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970918	EXPEDITED (15-DAY)		HO	NVSC2020ES177786		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Behaviour Disorder	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (Dia)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Diethylamine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Salazopyrine	S	Oral		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Gastro-Resistant Tablet	Not Reported
	Sulfasalazine	S	Oral	Gastro-Resistant Tablet	Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
	Topicort [Desoximetasone]	S	Oral		Not Reported
	Winpred	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17971377	EXPEDITED (15-DAY)		OT	NVSC2020US183789		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17972152	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-018147			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	12776517	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076645		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituximab	S	Intravenous drip	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	12911484	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2000-000013		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Rheumatoid Arthritis; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	1 Df, Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S		1 Gram, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Dorzolamide Hcl/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Methotrexate			C	Unknown	15 Milligram, Qd		Not Reported
	Estrogel			C	Unknown	0.6 %, Tid		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Microgram, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Milligram		Not Reported

Ergocalciferol	C	Unknown	1 Df, Qwk		Not Reported
Calcium	C	Unknown	500 Mg, Qd		Not Reported
Potassium Chloride	C	Unknown	1500 Mg, Qd		Not Reported
Estradiol	C	Unknown	0.6 %, Tid		Not Reported
Gravol	C	Unknown			Not Reported
Baclofen	C	Unknown	10 Milligram, Bid		Not Reported
Levaquin	C	Unknown	500 Milligram, Qd		Not Reported
Morphine	C	Unknown			Not Reported
Zingiber Officinale	C	Oral	500 Mg, Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	13049424	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016048704		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Condition Aggravated; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip		Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Estradiol	C	Unknown	0.6 Percent, Tid	Not Reported
Estradiol	C	Unknown	Unk	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	320 Mg, Qd	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Xalatan	C	Ophthalmic	50 Milligram, Qd	Not Reported
Xalatan	C	Unknown	Unk	Not Reported
Xalatan	C		50 Microgram, Qd	Not Reported
Xalatan	C		Unk, Solution Opthalmic	Not Reported
Dorzolamide Hcl/Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
Potassium Chloride	C		1500 Milligram, Qd	Not Reported
Potassium Chloride	C	Unknown	Unk	Not Reported
Zingiber Officinale	C	Unknown	500 Mg, Unk	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
Baclofen	C	Unknown	10 Mg, Bid	Not Reported
Levaquin	C		500 Mg, Qd For 10 Days	Not Reported
Levaquin	C		Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	500 Milligram, Qd	Not Reported

	Gravol		C	Unknown	Unk	Not Reported
	Prednisone		C		5 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	13153192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005886		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Cyclobenzaprine			C	Unknown	10 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram, Qd		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Prednisolone Acetate			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	13519848	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-000478		56 YR	Male	CAN

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

C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Orencia	S	Unknown		Bristol Myers Squibb
	Apo-Leflunomide	S	Unknown		Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Gram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline Hcl	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown		Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	7 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Q2wk	Not Reported
	Actemra	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Oxycodone	C	Unknown	10 Milligram	Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	14704614	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012672		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Ev 2 Weeks(Qow); Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Ev 4 Weeks		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (Qw)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Coversyl			C				Not Reported
	Ergocalciferol			C		2000 International Unit		Not Reported
	Leucovorin			C				Not Reported
	Folinic Acid			C				Not Reported
	Perindopril Erbumine			C	Oral	4 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	14917725	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-071465			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	577 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	577 Absent	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	577 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	577 Absent	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	577 Milligram	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	577 Milligram	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	577 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	577 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported

Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	577.0 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	577 Absent		Not Reported
Desoximetasone	C	Oral	Unk		Not Reported
Cortisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	14921997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044070			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	15621786	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557110-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	15622674	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557515-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	15635424	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-106079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	15935155	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656851-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

	Acetaminophen And Codeine Phosphate	C		Not Reported
	Leflunomide	C	Oral	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C		Not Reported
	Synthroid	C		Not Reported
	Tylenol W/Codeine No. 3	C		Not Reported
	Codeine	C		Not Reported
	Phosphoric Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	15978140	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)	200 Milligram, Bid		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16382249	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-107627		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Skin Reaction; Synovitis; White Blood Cell Count Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16396768	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2809469-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not			Not Reported

					otherwise specified)					
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16657676	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1084356			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Oral			Ivax
	Ciclosporin			S	Oral			Ivax
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16700535	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2885154-00		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Route: Suspension Intra-Articular		Not Reported
	Triamcinolone Acetonide			S				Not Reported

Antibody Present; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Wheelchair User	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S		Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Naproxen	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S		Not Reported
	Prednisone	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Triamcinolone Hexacetonide	S		Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16813820	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201906-001612			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Vein Occlusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod, Film-Coated Tablet,		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod, Film-Coated Tablet,		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet,		Concordia
	Cellcept			C		Unk		Not Reported
	Prednisolone			C	Oral	Unk		Not Reported
	Warfarin			C		Unk		Not Reported
	Magmitt			C		Unk		Not Reported
	Sodium Rabeprazole			C		Unk		Not Reported
	Sodium Rabeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16833020	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2933128-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Arava	C			Not Reported
	Plaquenil	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Simponi	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16842391	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2797897-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16848803	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201905-001472			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Dizziness Postural	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Macitentan			S	Oral	10 Mg,		Not Reported
	Prednisolone			S	Oral	4 Mg, Qd		Not Reported
	Imuran			S	Oral	100 Mg, Qd		Not Reported
	Methylprednisolone			S	Oral	32 Mg, Qd		Not Reported
	Ursodeoxycholic Acid			C		Unk		Not Reported
	Thyradin S			C		Unk, Unit Of Dose: Mcg		Not Reported

	Rabeprazole Na	C	Unk	Not Reported
	Rabeprazole Na	C		Not Reported
	Daiphen	C	Unk	Not Reported
	Daiphen	C		Not Reported
	Tracleer	C	Unk	Not Reported
	Azilva	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16857402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574079-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	16888902	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2951194-00			Female	CAN

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

Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Naproxen Sodium	C	Oral	Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17035514	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-107291			Female	CAN

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

Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown		Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17041153	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201802-000660			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercholesterolaemia; Low Density Lipoprotein Increased; Platelet Count Decreased; Retinal Tear; Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Prednisolone			S	Oral	50 Mg, Qd		Not Reported
	Prednisolone			S	Oral	45 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported

Prednisolone	S	Oral	35 Mg, Qd	Not Reported
Prednisolone	S	Oral	30 Mg, Qd	Not Reported
Prednisolone	S	Oral	27.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	25 Mg, Qd	Not Reported
Prednisolone	S	Oral	22.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	20 Mg, Qd	Not Reported
Prednisolone	S	Oral	17.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	15 Mg, Qd	Not Reported
Prednisolone	S	Oral	12.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	10 Mg, Qd	Not Reported
Prednisolone	S	Oral	9 Mg, Qd	Not Reported
Prednisolone	S	Oral	8 Mg, Qd	Not Reported
Prednisolone	S	Oral	7 Mg, Qd	Not Reported
Prednisolone	S	Oral	6 Mg, Qd	Not Reported
Sulfamethoxazole/Trimethoprim	S	Oral	1 Dosage Form, Qd	Not Reported
Amlodipine	S	Oral	10 Mg, Qd	Not Reported
Cellcept	C		Unk	Not Reported
Onealfa	C		Unk	Not Reported
Onealfa	C			Not Reported
Bonalon	C		Unk	Not Reported
Bonalon	C			Not Reported
Calblock	C		Unk	Not Reported
Avapro	C		Unk	Not Reported
Carvedilol	C		Unk	Not Reported
Natrix	C		Unk	Not Reported
Nexium	C		Unk	Not Reported
Nexium	C			Not Reported
Famotidine	C		Unk	Not Reported
Famotidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17543158	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022567		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	25 Milligram/ 2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution/ 300 Milligram, Q6wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Wellbutrin			C	Unknown	Tablet Extended Release		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17642991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029406		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17652040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002411			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Eosinophilia; Eosinophilic Myocarditis; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17675746	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096830			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Plaquenil			S		Unk		Sanofi
	Leflunomide			S		20 Mg, Qd (Every 1 Days)		Sanofi
	Methotrexate			S		Unk (Dose Is 12.5-25 Mg, Qwk)		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Hyzaar			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Effexor Sr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17703318	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202004002571			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atypical Pneumonia; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17705423	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202004003544			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Multiple Organ Dysfunction Syndrome; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Metoclopramide Hydrochloride			C		Unk		Not Reported
	Ciprofloxacine			C		Unk		Not Reported

Furosemide	C	Unk		Not Reported
Piperacilline/Tazobactam	C	Unk		Not Reported
Paracetamol	C	Unk		Not Reported
Lidocaine	C	Unk		Not Reported
Enoxaparin Sodium	C	Unk		Not Reported
Methylprednisolone	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17845179	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1241649		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Off Label Use; Rash Pustular	Darunavir			S	Oral	800mg		Teva
	Ritonavir Sandoz			S	Oral	1 Dosage Form		Not Reported
	Plaquenil			S	Oral	2 Dosage Form		Not Reported
	Arixtra 2.5 Mg/0.5 Ml Solution For Injection Pre-Filled Syringe			C	Subcutaneous	1 Dosage Form		Not Reported
	Clexane			C	Subcutaneous	1 Dosage Form		Not Reported
	Folina 5 Mg Capsule Molli			C				Not Reported
	Medrol 16 Mg Compresse			C				Not Reported
	Tazocin 4 G/0,5 G Polvere Per Soluzione Per Infusione			C	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported
	Kineret			C	Intravenous (not otherwise specified)	4 Dosage Forms		Not Reported
	Dibase 10.000 U.I./Ml Gocce Orali, Soluzione			C				Not Reported
	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			C	Oral	1 Dosage Form		Not Reported
	Omeprazole Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17848419	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201908-001809			Unknown	JPN

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

Exposure During Pregnancy; Exposure During Pregnancy; Foetal Death; Premature Delivery; Preterm Premature Rupture Of Membranes	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg, Qd	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg/Day And 400 Mg/Day Alternately	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg/Day And 400 M/Day Alternately	Concordia
	Prograf	C		Unk	Not Reported
	Persantin	C		Unk	Not Reported
	Prednisolone	C		Unk	Not Reported
	Edirol	C		Unk	Not Reported
	Edirol	C			Not Reported
	Viccillin	C		6 G, Qd	Not Reported
	Rinderon	C	Intramuscular	12 Mg, Qd	Not Reported
	Ritodrine	C		100 Mg, Qd	Not Reported
	Atonin-O	C	Subcutaneous	60 Units/Day	Not Reported
	Amoxicillin Trihydrate	C	Oral	1000 Mg, Qd	Not Reported
	Erythrocin	C	Oral	1200 Mg, Qd	Not Reported
	Ferrous Sodium Citrate	C	Oral	100 Mg, Qd	Not Reported
	K-Supply	C	Oral	1200 Mg, Qd	Not Reported
	Clexane	C	Subcutaneous	4000 Units/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17873558	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1244545		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash Morbilliform	Azithromycin			S	Oral	500 Mg		Not Reported
	Roactemra 20 Mg/Ml Concentrate For Solution For Infusion			S		1 Dosage Forms		Not Reported
	Clexane			S	Subcutaneous	8000 Ku		Not Reported
	Plaquenil			S	Oral	2 Dosage Forms		Not Reported
	Fidato 2 G Polvere Per			S	Intravenous (not	1 Dosage Forms		Not Reported

Soluzione Per Infusione		otherwise specified)			
Kaletra	S	Oral	4 Dosage Forms		Not Reported
Urbason Solubile	S	Intravenous (not otherwise specified)	1 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17908814	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046317		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Potassium Chloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17909403	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-202006006322			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Asphyxia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	400 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	200 Mg, Qod		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17952022	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051083			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S				Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

					otherwise specified)			
	Rituximab			S				Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17957260	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020245583		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Propofol			S		Unk		Pfizer
	Dolquine			S	Oral	200 Mg, 2x/Day (Every 12 Hours, A Compressed Breakfast And Dinner)		Not Reported
	Midazolam			S		Unk		Not Reported
	Midazolam			S				Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Ceftriaxone			S		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Rilast			C		Unk		Not Reported
	Manidon			C		Unk		Not Reported
	Omnic Ocas			C		Unk		Not Reported
	Kalpress			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970278	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-251695		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Electrocardiogram Qt	Hydroxychloroquine			S	Unknown	Unk		Sun
	Azithromycin			S	Intravenous (not	Unk		Sun

Prolonged; Electrocardiogram T Wave Abnormal; Hypermagnesaemia; Off Label Use

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970301	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3467594-00		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat Irritation	Kaletra			S	Oral			Not Reported
	Claritromicina			S	Unknown			Not Reported
	Dolquine			S	Unknown			Not Reported
	Azitromicina			S	Unknown	1000 Mg/ 1 Dia Y 500 Mg Resto		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970685	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2020SP006290		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Lidocaine			S	Epidural	Unk		Strides
	Prednisolone			S	Unknown	Unk		Not Reported
	Epoprostenol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported
	Fentanyl			S		Unk		Not Reported
	Fentanyl			S				Not Reported
	Morphine			S		Unk		Not Reported
	Morphine			S				Not Reported
	Bupivacaine			S		Unk		Not Reported
	Epinephrine			S	Epidural	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970697	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795793		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)		
	Rituximab		S	Intravenous drip		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz Xr		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970848	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795790			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970850	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795783		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Barr
	Ciclosporin			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970881	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-252190		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Mixed Liver Injury	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Tacrolimus (2694a)			S	Oral	8 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	800 Milligram, Daily		Not Reported
	Prednisona (886a)			S	Oral	20 Milligram, Daily		Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Milligram, Bid		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Daily		Not Reported

(2143su)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970888	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-252191		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Sulfamethoxazole And Trimethopim			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Milligram, Daily		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			S	Oral	2 Dosage Form, Daily		Not Reported
	Micafungina Sodica (8263so)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Piperacilina And Tazobactam			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970958	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795805		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17970972	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020026027		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Weekly (Qw)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Milligram		Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram, Once Daily (Qd)		Not Reported
	Folic Acid			S		Unk, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported

	Methotrexate	S		25 Milligram, Weekly (Qw)	Not Reported
	Prednisone	S	Oral	2 Dosage Form	Not Reported
	Xeljanz	S	Oral	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17971156	EXPEDITED (15-DAY)		OT	CA-SA-2020SA168638			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone			S	Oral	Unk		Sanofi
	Diclofenac Sodium			S		Unk		Not Reported
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	420 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	420 Mg, Qd		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17971381	EXPEDITED (15-DAY)		OT	CA-ACCORD-187497		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17971726	NON-EXPEDITED			US-ADVANZ PHARMA-202006006730			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chemical Burn; Hypersensitivity; Rash; Skin Exfoliation	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17971899	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050227			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported

Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
Naproxen	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	3 Milligram		Not Reported
Prednisone	S	Oral	5 Milligram, Bid		Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd		Not Reported
Triamcinolone	S	Unknown	Unk		Not Reported
Triamcinolone Hexacetonide	S	Intra-articular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17972354	EXPEDITED (15-DAY)		OT	CA-ACCORD-187152			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown	Not Specified		Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17972503	EXPEDITED (15-DAY)		HO	CA-ACCORD-186325		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer;	Mycophenolic Acid			S				Accord
	Methotrexate			S		Not Specified		Accord

Thrombosis	Tacrolimus	S		Accord
	Azathioprine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S		Not Reported
	Prednisone	C		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17972507	EXPEDITED (15-DAY)		OT	CA-ACCORD-187585		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Product Use Issue; Rheumatoid Arthritis; Sciatica	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Paracetamol			S				Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S		1 Every 1 Days		Not Reported
	Apo-Ramipril			S		1 Every 1 Days		Not Reported
	Folic Acid			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcuteneous		Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Levothyroxine			S		1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Intravenous Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Codeine/Paracetamol			C				Not Reported
	Caffeine/Dihydrocodeine/Paracetamol			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Ophthalmic	2 Every 1 Days		Not Reported
	Hydroxychloroquine			C		1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973042	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050936			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Tendon Disorder; Therapeutic Response Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973254	EXPEDITED (15-DAY)		DS	CA-ROCHE-2625986		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; Weight Increased	Gold	S	Unknown	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Indocid [Indometacin]	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Indomethacin [Indometacin]	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Fish Oil	C		Not Reported
	Cymbalta	C	Oral	Not Reported
	Ciprodex [Ciprofloxacin Hydrochloride;Dexamethasone]	C		Not Reported
	B Complex [Vitamin B Complex]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973267	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973281	EXPEDITED (15-DAY)		OT	CA-ACCORD-187305		67 YR	Female	CAN

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

Leflunomide	S	Oral			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown	Not Specified		Not Reported
Naproxen	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973479	EXPEDITED (15-DAY)		HO, OT	BE-ACCORD-187320			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Supraventricular Tachycardia	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973481	EXPEDITED (15-DAY)		OT	CA-ACCORD-187304		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Minocycline			S	Unknown	Not Specified		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

	Xeljanz	S	Unknown	2 Every 1 Days	Not Reported
	Amoxicillin/Clavulanate Potassium	C	Unknown		Not Reported
	Amoxil	C	Unknown		Not Reported
	Bacillus Calmette-Guerin Vaccine	C	Intravenous (not otherwise specified)		Not Reported
	Gold	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S			Not Reported
	Bacillus Calmette-Guerin Vaccine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973838	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-252339		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Compri...			S	Oral	2 Dosage Form, Daily		Not Reported
	Hidroxicloroquina Sulfato (2143su)			S	Oral			Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973940	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020252435		35 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Drug	Medrol			S	Oral	4 Mg, 1x/Day		Pfizer

Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Panniculitis; Product Use In Unapproved Indication; Pruritus; Rash; Rash Papular	Clexane		S	Subcutaneous	0.4 Ml, 1x/Day	Not Reported
	Clexane		S			Not Reported
	Fen Le [Hydroxychloroquine Sulfate]		S	Oral	0.1 G, 3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973948	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050903		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	480 Milligram, Qmo		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	Unk, 1 Eevry 1 Week		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram, Qd		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Aclasta			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Lomotil [Loperamide Hydrochloride]			C	Unknown	Unk		Not Reported

	Nasonex	C	Unknown	Unk, Spray Metered Dose	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973954	EXPEDITED (15-DAY)		HO	LU-ROCHE-2631530		84 YR	Male	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rytmonorm			S	Oral			Not Reported
	Asaflow			C	Oral	Chronic Treatment		Not Reported
	Betaferon			C	Subcutaneous			Not Reported
	Theralene			C	Oral	Chronic Treatment		Not Reported
	Clexane			C	Subcutaneous			Not Reported
	Allopurinol			C	Oral			Not Reported
	Solumedrol			C	Intravenous (not otherwise specified)			Not Reported
	Rocephin [Ceftriaxone]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973961	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1794874		43 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Arthropathy; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium	S	Unknown		Actavis
	Prednisone	S	Unknown		Actavis
	Actemra	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Plaquenil	S	Oral	1 Dosage Forms Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973987	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795037			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	420 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	420 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown	2 Gram Daily;		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974005	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050990			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	50 Milligram/Sq. Meter, Q2wk		Not Reported
	Prednisone			S	Oral	1.3 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported
	Triamcinolone Hexacetonide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974006	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Unk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Milligram		Not Reported
	Calcium			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Unknown			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2020-051221

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974265	EXPEDITED (15-DAY)		OT	CA-ACCORD-187303		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	Not Specified		Accord
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Oral	Not Specified		Not Reported
	Meloxicam			C	Oral	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974392	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795691			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974403	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795780		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Leflunomide			S	Unknown			Barr
	Ciclosporin			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate	S	Oral			Not Reported
Neoral	S	Unknown			Not Reported
Neoral	S	Oral			Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974404	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795730		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	20 Mg		Barr
	Methotrexate			S	Subcutaneous	20 Mg		Barr
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795779		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Barr
	Ciclosporin			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Neoral	S	Subcutaneous			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Intravenous drip			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz Xr	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974414	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, 40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974422	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795575			Female	CAN

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

Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate	S	Unknown		Barr
	Ciclosporin	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974682	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795584		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974714	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795756			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974725	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1795724		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Alendronic Acid			S	Unknown			Actavis
	Ciclosporin			S	Unknown			Ivax
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974726	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795762			Female	CAN

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

Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Ciclosporin	S	Subcutaneous	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974742	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051281			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Infliximab			S	Unknown	5 Milligram, Qwk		Not Reported

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	3 Milligram, 2 Every 1 Day	Not Reported
	Prednisone	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974775	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES181864		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis
	Azitromicina			S	Oral	500 Mg, Q24h		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Q24h		Not Reported
	Enoxaparina			S	Subcutaneous	80 Mg, Q12h (Cada 12h)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974783	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795462		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Orencia	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tofacitinib	S	Unknown			Not Reported
Gabapentin	C	Oral	1200 Milligram Daily;		Not Reported
Tylenol	C	Unknown	2600 Milligram Daily;		Not Reported
Xeljanz	C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974799	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795773		63 YR	Female	CAN

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

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974833	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795694		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquin			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974935	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974936	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974937	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795577			Female	CAN

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

Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate	S	Unknown	Barr
	Ciclosporin	S	Unknown	Ivax
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974983	NON-EXPEDITED			US-SA-2020SA169452			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Onychomadesis	Hydroxychloroquine			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Prednisone			S		3.5 Mg, Qd, 1 Mg Night And 2.5 Mg In Morning		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975049	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795760		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Adalimumab		S	Unknown	80 Milligram Daily;	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tofacitinib Citrate		S	Unknown		Not Reported
	Tylenol Arthritis		C		2600 Milligram Daily;	Not Reported
	Xeljanz		C	Oral		Not Reported
	Gabapentin		C	Oral	1200 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975072	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975073	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795741			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975170	EXPEDITED (15-DAY)		DE, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2020026916			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukocytosis;	Clopidogrel			S	Oral	75 Milligram, Qd		Macleods

Pyrexia; Respiratory Distress; Sepsis	Clopidogrel	S	Oral	300 Milligram	Macleods
	Aspirin	S	Oral	75 Milligram, Qd	Not Reported
	Aspirin	S	Intravenous (not otherwise specified)	250 Milligram	Not Reported
	Methylprednisolone	S	Unknown	1 Milligram/Kilogram	Not Reported
	Tirofiban	S	Intravenous (not otherwise specified)	25 Mg/Kg Body	Not Reported
	Tirofiban	S	Intravenous (not otherwise specified)	0.15 Ug/Kg Body Per Minute For 48 Hours	Not Reported
	Fondaparinux Sodium	S	Subcutaneous	2.5 Milligram, Qd, Solution For Injection	Not Reported
	Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975209	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051049		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Intentional Product Use Issue; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin	Orencia			S	Vaginal	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	480 Milligram, Qmo		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral	100 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported
	Myochrysine			S	Intramuscular	60 Milligram, Q3wk		Not Reported
	Nortriptyline			S	Oral	10 Milligram		Not Reported
	Oxycontin			S	Unknown			Not Reported

Lesion; Sleep Disorder; Treatment Failure	Sulfasalazine	S	Oral	2.5 Gram	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Lomotil [Loperamide Hydrochloride]	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Nasonex	C	Unknown		Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Perphenazine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975245	EXPEDITED (15-DAY)		OT	CA-FRESENIUS KABI-FK202006656		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic	Clindamycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Moxifloxacin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Pantoprazole (Manufacturer Unknown)			S	Unknown			Not Reported
	Penicillin G (Manufacturer Unknown)			S	Unknown			Not Reported

Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Penicillin Nos	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Moxifloxacin Hydrochloride	S	Unknown		Not Reported
	Clarithromycin	S	Intravenous (not otherwise specified)		Not Reported
	Clarithromycin	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Cefalexin	S	Unknown		Not Reported
	Cefalexin	S	Unknown		Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enalapril	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Hydralazine	S	Unknown		Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Levofloxacin	S	Unknown		Not Reported
	Losartan	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Metoprolol	S	Unknown		Not Reported
	Rabeprazole Sodium	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported
	Ciprofloxacin	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Gold	C	Unknown	Gold Injections	Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

Prednisone	C	Unknown	Not Reported
Patiromer Sorbitex Calcium	C	Unknown	Not Reported
Saccharated Iron Oxide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975298	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1795571		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Ciclosporin	S	Unknown	150 Milligram Daily;	Ivax
	Alendronate Sodium	S	Unknown		Actavis
	Codeine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975299	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795527			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr

	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975316	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-735994		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pustular	Novorapid			S	Subcutaneous	Unk		Novo Nordisk
	Atorvastatine [Atorvastatin]			S	Oral	20 Mg, Qd		Not Reported
	Lantus			S	Subcutaneous	Unk		Not Reported
	Furosemide			S	Oral	120 Mg, Qd		Not Reported
	Furosemide			S	Oral	Dose Decreased		Not Reported
	Advagraf			S	Oral	1 Df, Qd		Not Reported
	Cortancyl			S	Oral	7.5 Mg, Qd		Not Reported
	Azithromycine			S	Oral	Unk		Not Reported
	Flecaine			S	Oral	100 Mg, Qd		Not Reported
	Aranesp			S	Subcutaneous	40 Mg, Qw		Not Reported
	Atenolol			S	Oral	50 Mg, Qd		Not Reported
	Cholecalciferol			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Loxen L P			S	Oral	100 Mg, Qd		Not Reported
	Allopurinol			S	Oral	300 Mg, Qd		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975320	EXPEDITED (15-DAY)		OT	CA-SA-2020SA169760			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Cortisone Acetate			S		25 Mg		Not Reported
	Cortisone Acetate			S	Oral	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Diclofenac Sodium			S		Unk		Not Reported
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Methotrexate			S	Oral	2 Df, Qd (2 In 1 Days)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S	Oral	Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Sunconjunctival	40 Mg		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975324	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975343	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax

	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975738	EXPEDITED (15-DAY)		HO	IT-SA-2020SA168703			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Erythema; Off Label Use; Rash Maculo-Papular	Enoxaparin Sodium			S	Subcutaneous	1 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17975818	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK202006635			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torsade De Pointes; Ventricular Arrhythmia	Propofol (Manufacturer Unknown)			S	Unknown	Unknown		Not Reported
	Azithromycin (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	On Days 2 Through 5		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976089	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20151202281		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Rash; Treatment Failure; Urticaria	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976279	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050244		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Subcutaneous	1 Dosage Form, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Apo-Gabapentin			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported

Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celebrex	S	Oral	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Celecoxib	S			Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Myochrysine	S	Intramuscular	60 Milligram	Not Reported
	Nortriptyline	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Fentanyl	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Fish Oil	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Omega 3 6 9 [Fish Oil]	C	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Vitamin B3	C	Unknown	Unk	Not Reported

Esomeprazole	C	Unknown	Unk		Not Reported
Genteal [Carmellose Sodium;Hypromellose]	C	Unknown	Unk		Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976289	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050261		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q3wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Arava			S	Oral	20 Milligram, Qmo		Not Reported
	Celebrex			S	Other	Occlusive Dressing Technique		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd Tablet		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk Solution		Not Reported
	Oxycontin			S	Unknown	Extended Release		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported

Aclasta	C	Intravenous (not otherwise specified)	Solution	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Cyanocobalamin	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Nasonex	C	Unknown	Spray, Metered Dose	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Vitamin A Nos	C	Unknown	Unk	Not Reported
Vitamin B1 Nos	C	Unknown	Unk	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976323	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976324	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976337	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052354		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Methotrexate			C	Unknown	20 Milligram, Qwk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17977152	EXPEDITED (15-DAY)		OT	NVSC2020ES181858		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Pain	Hydroxychloroquine			S	Oral	200 Mg, Qd		Novartis
	Kaletra			S	Oral			Not Reported
	Omeprazole			C	Oral	20 Mg, Qd		Not Reported
	Paracetamol			C	Oral	1 G, Q8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17977167	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3467950-00		47 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral	400 Mg/100 Mg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Co-Amoxi			C				Not Reported
	Symbicort Turbohaler			C				Not Reported
	Jardiance			C				Not Reported
	Clexane			C				Not Reported
	Xultophy			C				Not Reported
	Emla			C				Not Reported
	Dafalgan			C				Not Reported
	Coversum N			C				Not Reported
	Pravastatine			C				Not Reported
	Nacl			C				Not Reported
	Vannair			C		As Necessary / In Reserve		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17977267	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood	Ciclosporin			S	Unknown			Ivax

Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17977268	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795698			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	11433670	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram, Qd		Not Reported
	Apo Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Naprosyn [Naproxen]			S	Unknown	Unk Prn		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Naproxen			S	Unknown	Unk Unk, Prn		Not Reported
	Enbrel			S		Unk		Not Reported
	Asa			C	Unknown	81 Milligram		Not Reported

	Ramipril	C	Unknown	Unk	Not Reported
	Cardio Aspirin	C	Unknown	81 Milligram	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Lantus	C	Subcutaneous	Unk	Not Reported
	Insulin [Insulin Human]	C	Unknown	Unk	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
	Calcium [Calcium Gluconate]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk Prn	Not Reported
	Lozide [Gliclazide]	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Vitamin D Nos	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	11444767	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015088930		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness;	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	20 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	S	Unknown	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Unk (7 Years)	Not Reported
	Orencia	S	Unknown	750 Milligram, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram, Unk (9 Months)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram, Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram, Bid (5 Months)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Bid	Not Reported
	Simponi	S	Unknown	50 Milligram, Unk (3 Years)	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Unk	Not Reported
	Apo-Prednisone	S	Oral	Unk Unk, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram 1 Every 12 Hours	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	11607841	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-JNJFOC-20150923280		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Gait Disturbance; General Physical Health Deterioration; Glossodynia; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infection; Infusion Related Reaction; Injury; Joint Range Of Motion Decreased; Joint Swelling; Knee	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Zyrtec			S	Oral			Johnson And Johnson
	Zyrtec			S	Unknown			Johnson And Johnson
	Reactine (Cetirizine Dihydrochloride)			S	Oral			Johnson And Johnson
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg/0.8 Ml		Not Reported

Arthroplasty; Memory Impairment; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Off Label Use; Pain; Pain In Extremity; Pemphigus; Pericarditis; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative Arthritis; Sleep Disorder; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Noncompliance; Type 2 Diabetes Mellitus; Walking Aid User; Weight Decreased; Wound; Wound Infection	Humira	S	Sunconjunctival		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therpay Duration 11 Monts	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Subcutaneous		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravesical	Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported

Hydroxychloroquine Sulfate	S	Urethral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Topicort	S	Subcutaneous	Not Reported
Topicort	S	Topical	Not Reported
Topicort	S	Oral	Not Reported
Topicort	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Cosentyx	S		Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported

	Atasol [Paracetamol]	C	Unknown	Not Reported
	Ibuprofen	C		Not Reported
	Prinivil	C	Unknown	Not Reported
	Cholecalciferol	C		Not Reported
	Zyrtec /00884302/	C		Not Reported
	Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	11745381	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015120647		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rocuronium			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Unknown			Not Reported
	Penicillin	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Rocuronium Bromide	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	11923531	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539429-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Drug Ineffective; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	12642905	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016102459		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	400 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	12727842	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-072673		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Benign Neoplasm; Bladder Operation; Disability; Drug Ineffective; Fatigue; Headache; Influenza Like Illness; Malaise; Peripheral Swelling; Spinal Pain; Urinary Tract Infection; Vaginal Haematoma	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Qmo		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	2000 Dosage Form	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Vitamin D2	C	Oral	2000 Unit, Qd	Not Reported
	Vitamin B12 [Cyanocobalamin]	C	Sublingual	1000 Mg, Qd	Not Reported
	Multivitamin [Ascorbic Acid;Biotin;Calcium Pantothenate;Cyanocobalamin	C	Oral	Unk, Qd	Not Reported
	Prednisone	C	Oral	4 Tab, Qd	Not Reported
	Prednisone	C	Oral	3 Tab, Qd	Not Reported
	Prednisone	C	Oral	2 Tab, Qd	Not Reported
	Prednisone	C	Oral	1 Tab, Qd	Not Reported
	Depo-Medrol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	12945877	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016158750		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	7.5 Milligram, Unk	Not Reported
Methotrexate	S	Subcutaneous	7.5 Milligram, Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid (For 8 Years)	Not Reported
Methotrexate Sodium	S	Unknown	7.5 Milligram Unk (For 8 Years)	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	50 Milligram, Bid	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	7.5 Milligram, Bid	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not		Not Reported

			otherwise specified)		
	Arthrotec	C	Unknown	50 Milligram, Bid	Not Reported
	Gold	C		Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Plaquenil	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	13210578	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA020159			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Injury; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	13571360	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017077269		61 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Unknown	50 Milligram, Qwk	Amgen
	Methotrexate Sodium	S	Oral	25 Milligram, 1x/Day	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, 1x/Day	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	13805299	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017112357		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Glaucoma Surgery; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Prednisone	C	Oral	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Arava	C		Unk		Not Reported
Codeine	C	Unknown	Unk		Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	13855498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070302		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Methotrexate		C	Subcutaneous	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	13913466	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017129066		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	14212488	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017173378		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram		Not Reported

	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15383755	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082928			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15428600	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016087558		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported

	Hydroxychloroquine		S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous	400 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15620004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556866-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15620814	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556952-00		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Humira			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Actonel	C	Unknown	Not Reported
	Risedronate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15621780	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2557337-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergic Oedema; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Discomfort; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty;	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Urticaria	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Viread	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15625955	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557437-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15735711	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2595527-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Muscular Weakness; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Pre-Filled		Not Reported

	Enbrel			C			Syringe			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15923770	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2653534-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Intramuscular	Not Reported
	Sulfasalazine	S	Intramuscular	Not Reported
	Sulfasalazine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

	Rituxan	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15930941	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655659-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Acetaminophen W/Codeine Phosphate			C					Not Reported
	Meloxicam			C					Not Reported
	Methotrexate			C	Unknown				Not Reported
	Synthroid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	15935428	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657038-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Actemra	S	Unknown	Not Reported
	Cimzia	C	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	16336131	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2788286-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Disability; Dyspepsia; Dyspnoea; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	16402022	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2806410-00		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Toe	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rub A535			C				Not Reported
	Asa			C				Not Reported
	Folic Acid			C				Not Reported
	Calcium			C				Not Reported

Amputation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	16408704	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2019081366		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1.5 Gram Tio		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	162.0 Milligram		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			C		20 Milligram		Not Reported
	Kineret			C		Unk		Not Reported
	Rituxan			C		Unk		Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	16485230	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2835174-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	16698324	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2885038-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Blood Cholesterol Increased; Bronchitis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Hypertension; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Sleep Disorder; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Vitamin D			C	Oral			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C				Not Reported

	Hydromorphone			C	Oral				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Calcium Carbonate			C	Oral				Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown				Not Reported
	Desoximetasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	16849905	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2937811-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	16994530	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-102576		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, (2 Every 1 Week)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram (2 Every 1 Week)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram (2 Every 1 Week)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Vioxx			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram (2 Every 1 Day)		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17559216	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021540		40 YR	Male	CAN

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

Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Arava	S	Oral	Unk		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Desoximetasone	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17673960	NON-EXPEDITED			US-AMGEN-USASP2020061784		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17763559	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232931		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Kaletra			S	Oral	4 Dosage Forms Daily; Unit Dose: 2 Df Kaletra		Not Reported

					200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 C		
	Kaletra		S				Not Reported
	Dolquine		S	Oral	400 Milligram Daily; Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported
	Dolquine		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17811925	EXPEDITED (15-DAY)		HO	CA-ADVANZ PHARMA-202005005294			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cortisone			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17830292	EXPEDITED (15-DAY)		HO, OT	NVSC2020FR145080		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bundle Branch Block; Cardiotoxicity; Conduction Disorder; Decreased Appetite; Drug Ineffective; Dysphagia; Dysphonia; Left Ventricular Hypertrophy; Muscle Disorder; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd, 7.4 Mg/Kg/Day)		Novartis
	Hydroxychloroquine			S				Novartis
	Fenofibrate			S	Unknown	100 Mg, Qd		Not Reported
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Chloroquine			S				Not Reported
	Ranitidine			C	Unknown	300 Mg, Qd		Not Reported
	Clopidogrel			C	Unknown	75 Mg, Qd		Not Reported
	Acetylsalicylic Acid			C	Unknown	75 Mg, Qd		Not Reported
	Tramadol/Paracetamol			C	Unknown	Unk		Not Reported

	Clobetasol	C	Unknown	1 Application/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17831439	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-025875		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17847279	EXPEDITED (15-DAY)		CA	NVSC2020US148890			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Premature Baby	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Novartis
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17851573	EXPEDITED (15-DAY)		OT	NVSC2020US151024			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17851592	EXPEDITED (15-DAY)		OT	NVSC2020US151023			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17859367	EXPEDITED (15-DAY)		DE, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-249218		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Sun
	Hidroxicloroquina (2143a)			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Metilprednisolona			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17880984	EXPEDITED (15-DAY)		DE	ES-ROCHE-2615723		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral	500 Mg Dia		Not Reported
	Dolquine			S	Oral			Not Reported
	Dolquine			S				Not Reported
	Kaletra			S	Oral	2u Cada 12h		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17887103	EXPEDITED (15-DAY)			SK-ADVANZ PHARMA-202006006304			Unknown	SVK

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

Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	Unk	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S			Concordia
	Azithromycin	C		Unk	Not Reported
	Kaletra	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17891511	EXPEDITED (15-DAY)		DE, OT	IT-SHIRE-IT202019294			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	0.4 Gram Per Kilogram, Qd		Shire
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lopinavir + Ritonavir			S	Unknown			Not Reported
	Lopinavir + Ritonavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17919210	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020US170635		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Muscular Weakness; Nausea; Overdose; Poisoning; Somnolence; Suicide Attempt; Ventricular Tachycardia; Vomiting	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg (20 Tablets)		Novartis
	Methotrexate			S	Unknown	2.5 Mg (30 Tablets)		Not Reported
	Prednisone			S	Unknown	10 Mg (30 Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17925685	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3454213-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17931239	EXPEDITED (15-DAY)		HO, OT	NVSC2020FR169317		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Pyrexia	Amoxicillin			S	Oral	3 G, Qd		Novartis
	Hydroxychloroquine			S	Oral	800 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17965007	EXPEDITED (15-DAY)		HO, OT	NVSC2020LV179662		12 YR	Female	LVA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pneumonitis; Systemic Lupus Erythematosus; Weight Decreased	Azithromycin			S	Unknown	Unk		Novartis
	Methylprednisolone			S	Unknown	4 Mg, Qd		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Roactemra			S				Not Reported
	Roactemra			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	375 Mg/M2, Qw		Not Reported

	Mycophenolate Mofetil	C	Unknown	For Short Time Period (1-2 Weeks).Stopped Due To Skin Eruptions	Not Reported
	Cyclophosphamide	C	Unknown	For Short Time Period (1-2 Weeks)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17976512	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2632494		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic	Ceftriaxone			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown	(+/- 1 Mg/Kg Day)		Not Reported
	Methylprednisolone			S	Intravenous bolus			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	3 Bolus		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17976732	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202006006830			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Vision Blurred	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17976760	EXPEDITED (15-DAY)		OT	CA-SA-2020SA169692			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Cortisone Acetate			S	Unknown			Not Reported

Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Desoximetasone	S	Oral	Unk	Sanofi
	Arava	S	Unknown		Sanofi
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown		Sanofi
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Sanofi
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Fosamax	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported

	Sulfathalidine	S	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17976786	NON-EXPEDITED			US-ADVANZ PHARMA-202006006860			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S		Unk, (Plaquenil)		Concordia
	Aubagio			C	Oral	14 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977000	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050673			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Dolquine			S	Other	400 Milligram		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977002	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050756			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gram, Qd		Not Reported
	Ceftriaxona [Ceftriaxone]			S				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	200 Milligram, Bid		Not Reported

	Hidroxicloroquina [Hydroxychloroquine]	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977004	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050768			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gram, Qd		Not Reported
	Ceftriaxona [Ceftriaxone]			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Qd		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977026	NON-EXPEDITED			US-ADVANZ PHARMA-202006006883			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Malaise; Nausea; Night Sweats; Nightmare; Weight Decreased	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977369	EXPEDITED (15-DAY)		OT	NVSC2020IT184454		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Methylprednisolone			S	Unknown	4 Mg, Qd		Not Reported
	Sarilumab			C	Unknown	200 Mg, Q2w		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977372	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1794058		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pustular	Allopurinol			S	Oral	300 Mg		Actavis
	Atenolol			S	Oral	50 Mg		Not Reported
	Atorvastatine			S	Oral	20 Mg		Teva
	Azithromycine			S	Oral			Not Reported
	Cholecalciferol			S	Oral			Not Reported
	Furosemide			S	Oral	120 Mg		Not Reported
	Lantus			S	Subcutaneous			Not Reported
	Novorapid			S	Subcutaneous			Not Reported
	Advagraf 1 Mg, Gelule A Liberation Prolongee			S	Oral	1 Dosage Form		Not Reported
	Cortancyl 5 Mg, Comprime			S	Oral	7.5 Mg		Not Reported
	Flecaine 100 Mg, Comprime Secable			S	Oral	100 Mg		Not Reported
	Aranesp			S	Subcutaneous	40 Mcg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Loxen L P 50 Mg, Gelule A Liberation Prolongee			S	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977486	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052984			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown	2 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17977667	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3469904-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17978321	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-252337		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina (2143a)			S	Oral	400 Mg C/12 Horas Seguido De 200 Mg C/12 Horas		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Co...			S	Oral	2 Dosage Form, Bid		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
	Omeprazol (2141a)			C	Unknown			Not Reported
	Deprax 100 Mg Comprimidos Recubiertos Con Pelicula Efg			C	Unknown	Unk		Not Reported
	Rhinom - Rhinomer Nasal Spray			C	Unknown	Unk		Not Reported
	Manidon Retard 120 Mg Comprimidos De Liberacion Prolongada			C	Unknown	Unk		Not Reported
	Sintrom			C	Unknown			Not Reported
	Paracetamol (12a)			C	Unknown			Not Reported
	Duphalac 10 G Solucion Oral En Sobre			C	Unknown			Not Reported
	Bisoprolol 2,5 Mg Comprimido			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Escitalopram (2858a)			C	Unknown	Unk		Not Reported
	Humalog			C	Unknown	Unk		Not Reported
	Furosemida (1615a)			C	Unknown	Unk		Not Reported
	Alprazolam 1 Mg Comprimido			C	Unknown	Unk		Not Reported
	Sinemet Plus Retard 25 Mg/100 Mg Comprimidos De Liberacion			C	Unknown	Unk		Not Reported

	Prolongada								
	Atrovent		C	Unknown	Unk				Not Reported
	Noctamid 1 Mg Comprimidos		C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17978569	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1796145		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Medroxyprogesterone Acetate			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17978581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1796206			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Lyrica	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Unknown	Solution Subcutaneous	Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17978587	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-187905		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Cefazolin			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Arava			C				Not Reported
	Naproxen			C				Not Reported
	Viread			C				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17978715	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1796174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased;	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17978738	EXPEDITED (15-DAY)		HO	NVSC2020ES176724		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Hydroxychloroquine			S	Oral	400 Mg, Qd (Dia)		Novartis
	Azitromicina			S	Oral	500 Mg, Qd (Dia)		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Symbicort			S	Respiratory (inhalation)	2 Df, 2-2-2 (160 Microgramos/4,5 Microgramos)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17978757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052298		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin	S	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979024	EXPEDITED (15-DAY)		LT	NVSC2020ES187015		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Mixed Liver Injury	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Interferon Beta-1b			S	Subcutaneous	30 Ug, Qd		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Rezolsta			S	Oral	1 Df, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1796084		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy;	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil	S	Unknown	Teva
	Pregabalin	S	Unknown	Teva
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979147	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200635574		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979185	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796191		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Celecoxib			S	Oral			Teva
	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Acetaminophen			C				Not Reported
	Aclasta			C				Not Reported
	Ergocalciferol			C				Not Reported
	Esomeprazole			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Lomotil			C				Not Reported
	Loperamide			C				Not Reported
	Nasonex			C				Not Reported
	Oxycodone			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Prednisone			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Trazodone			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979385	EXPEDITED (15-DAY)		HO	NVSC2020ES181884		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Encephalopathy; Pancytopenia	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis
	Amoxicillin And Clavulanate			S	Intravenous (not otherwise specified)	1 Gr Each 12 Hours X 5 Days Following 1gr Each 8 Hours X 6 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979397	EXPEDITED (15-DAY)		LT	NVSC2020US187343		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Sars-Cov-2 Test Positive	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Bid		Novartis
	Pyridostigmine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979622	EXPEDITED (15-DAY)		OT	NVSC2020ES184584		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Long Qt Syndrome	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979685	EXPEDITED (15-DAY)		OT	NVSC2020FR186673		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Ciprofloxacin			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17979926	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020106003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980001	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1059852		33 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticaria	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Cefixime			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan
	Deltacortene			S	Oral	5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980073	EXPEDITED (15-DAY)		LT, OT	NVSC2020US187347		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Respiratory Failure; Sars-Cov-2 Test Positive	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S				Novartis
	Methotrexate			C	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			C				Not Reported
	Oseltamivir			C	Unknown	Unk		Not Reported
	Vancomycin			C	Unknown	Unk		Not Reported
	Piperacillin			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 Mg/Kg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980121	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q3wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Celebrex			S	Unknown	Unk, Route: Occlusive Dressing Technique		Not Reported
	Docosahexaenoicacid/Eicosapentaenoic Acid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported

Oxycontin	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	2.5 Gram, Qd	Not Reported
Vitamin B1 [Thiamine]	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Cholecalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Nasonex	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
Vitamin B6	C	Unknown	Unk	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980122	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Phosphoric Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980138	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052216		41 YR	Female	USA

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

C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980141	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2 Every 1 Week		Not Reported
	Leflunomide			S		20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980143	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053119			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Bid		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980256	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053034			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

Ilaris	S	Unknown	Unk			Not Reported
Ilaris	S					Not Reported
Leflunomide	S	Unknown	Unk			Not Reported
Leflunomide	S					Not Reported
Methotrexate	S	Unknown	Unk			Not Reported
Remicade	S	Unknown	Unk			Not Reported
Remicade	S					Not Reported
Sulfasalazine	S	Unknown	Unk			Not Reported
Sulfasalazine	S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17980395	EXPEDITED (15-DAY)		DE, LT, OT	ES-ABBVIE-20K-144-3467451-00		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Kaletra			S	Oral	532 Mg/133.2 Mg/Dia		Not Reported
	Levofloxacino			S	Unknown	500 Mg/Dia Iv		Not Reported
	Azitromicina			S	Unknown	500 Mg/ Dia		Not Reported
	Digoxina			S	Unknown	0.5 Mg/Iv		Not Reported
	Dolquine			S	Unknown	800 Mg Un Dia, 400 Mg 4 Dias		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	12103915	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016021127		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Sodium Aurothiomalate	C		Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Gold	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	12284961	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016048021		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported

Humira	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	300 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	12635667	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016101720		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported

Toradol	S	Unknown	Unk		Not Reported
Prednisone	C	Unknown	7-10 Milligram, Unk		Not Reported
Tramadol	C	Unknown	100 Milligram, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	14625143	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018032018			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	14629084	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17851324	EXPEDITED (15-DAY)		OT	NVSC2020US151019			Unknown	USA

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

Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp	S	Transplacental	Maternal Dose: Unk	Novartis
	Betamethasone	S	Transplacental	Maternal Dose: Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17978611	EXPEDITED (15-DAY)		OT	CA-ACCORD-188264		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Gold			S		1 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Golimumab			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			C				Not Reported
	Ciclosporin			C				Not Reported
	Minocycline			C				Not Reported
	Prednisone			C		2 Every 1 Days		Not Reported
	Penicillamine			C				Not Reported
	Azathioprine			C		1 Every 1 Days		Not Reported
	Methotrexate			S	Parenteral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980505	EXPEDITED (15-DAY)		CA	US-CADILA HEALTHCARE			Unknown	USA

LIMITED-US-ZYDUS-052628

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cystic Kidney Disease; Delayed Foetal Renal Development; Dilatation Ventricular; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Zydus Pharm
	Leflunomide			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Levothyroxine Sodium			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980535	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252198		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980678	EXPEDITED (15-DAY)		OT	CA-ACCORD-188320		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Accord
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980688	EXPEDITED (15-DAY)		OT	CA-ACCORD-187940		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		1 Every 12 Hours		Not Reported
	Leflunomide			S				Not Reported
	Remicade			S		Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C				Not Reported
	Azathioprine			C				Not Reported
	Arthrotec			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980691	EXPEDITED (15-DAY)		OT	CA-ACCORD-188095		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980693	EXPEDITED (15-DAY)		OT	CA-ACCORD-187950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate			S				Accord
	Xeljanz			S				Not Reported
	Sulfasalazine			S				Not Reported
	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Codeine			S				Not Reported
	Celebrex			S				Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980695	EXPEDITED (15-DAY)		OT	CA-ACCORD-187942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S		1 Every 1 Weeks		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S		2 Every 1 Days	Not Reported
	Leflunomide	S		1 Every 1 Days	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported
	Sulfasalazine	C			Not Reported
	Bupropion/Bupropion Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980721	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1796198		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980724	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1796193			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980735	EXPEDITED (15-DAY)		CA, OT	US-AUROBINDO-AUR-APL-2020-031106			Unknown	USA

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

Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Hydrochlorothiazide	S	Transplacental	Unk		Aurobindo
	Indomethacin	S	Transplacental	Unk		Aurobindo
	Methotrexate	S	Transplacental	Unk		Eugia Pharma
	Deflazacort	S	Transplacental	Unk		Not Reported
	Chloroquine	S	Transplacental	Unk		Not Reported
	Hydroxychloroquine	S	Transplacental	Unk		Not Reported
	Methyldopa	S	Transplacental	Unk		Not Reported
	Leflunomide	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980762	EXPEDITED (15-DAY)		OT	CA-ACCORD-188173			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Aurothioglucose			S	Other			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Solution Intramuscular		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980765	EXPEDITED (15-DAY)		OT	CA-ACCORD-188253			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate			S	Unknown	Not Specified		Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Unknown	Solution Intramuscular		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980790	EXPEDITED (15-DAY)		LT, OT	CA-ACCORD-188771		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Avium Complex Infection; Osteomyelitis	Methotrexate			S	Oral			Accord
	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980819	EXPEDITED (15-DAY)		OT	CA-ACCORD-188338		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Prednisone	C	Unknown			Not Reported
Humira	S	Unknown			Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous, 1 Every 1 Weeks		Not Reported
Hydroxychloroquine	S	Endocervical			Not Reported
Methotrexate	S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980821	EXPEDITED (15-DAY)		OT	CA-ACCORD-188329		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Weight Decreased	Methotrexate			S	Subcutaneous			Accord
	Varicella Virus Vaccine/Live			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980912	EXPEDITED (15-DAY)		OT	CA-ACCORD-187959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Actemra			S	Subcutaneous	Not Specified		Not Reported

Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine		S	Subcutaneous	Not Specified	Not Reported
	Ciclosporin		S		Not Specified	Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Leflunomide		S	Oral		Not Reported
	Sodium Aurothiomalate		S	Parenteral		Not Reported
	Sulfasalazine		S	Unknown	Not Specified	Not Reported
	Ergocalciferol		C	Unknown	Not Specified	Not Reported
	Esomeprazole		C	Unknown		Not Reported
	Kevzara		C	Subcutaneous		Not Reported
	Magnesium		C		Not Specified	Not Reported
	Metformin		C	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980920	EXPEDITED (15-DAY)		OT	CA-ACCORD-188393			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown	Not Specified		Accord
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Varicella Virus Vaccine/Live			S	Intravenous (not			Not Reported

			otherwise specified)		
	Desoximetasone	C	Oral	Not Specified	Not Reported
	Diclofenac	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Varicella Virus Vaccine/Live	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980971	EXPEDITED (15-DAY)		HO	ES-ACCORD-188926		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use	Mycophenolic Acid			S				Accord
	Everolimus			S				Not Reported
	Hydroxychloroquine			S		400 Mg/12 Hours During The First Day, Then 200 Mg/12 H During 4-9 Days		Not Reported
	Lopinavir/Ritonavir			S		200/100 Mg Twice A Day For 14 Days		Not Reported
	Interferon Beta			S	Subcutaneous	250 Microg Every 48 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980974	EXPEDITED (15-DAY)		OT	CA-ACCORD-187900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported

	Infliximab		S	Intravenous (not otherwise specified)	1 Every 6 Weeks	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Bupropion		C	Oral		Not Reported
	Xeljanz		C			Not Reported
	Methotrexate		S	Unknown	1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980975	EXPEDITED (15-DAY)		OT	CA-ACCORD-187899		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	2 Every 1 Weeks		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980986	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-002082			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dyspepsia; Headache	Hydroxychloroquine Sulfate			S	Oral	200 Milligram		Ipca
	Fexofenadine Hydrochloride			C	Unknown	Unk		Not Reported
	Ferrous Fumarate			C	Unknown	Unk		Not Reported
	Levothyroxine Sodium			C	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	Unk		Not Reported
	Quinine Sulfate			C	Unknown	Unk		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17980987	EXPEDITED (15-DAY)		LT, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-002079			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Hydroxychloroquine			S	Oral	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17981062	EXPEDITED (15-DAY)		LT	NVSC2020ES185530		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Progression; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lopinavir,Ritonavir			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	12302836	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016051354		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Off Label	Enbrel			S	Unknown	Unk		Amgen

Use; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	Unk	Amgen
	Enbrel	S	Unknown	50 Milligram	Amgen
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	15622638	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557282-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported

	Prednisone Acetate	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	15934567	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656903-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	16693521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077005		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin	Abatacept			S	Unknown	750 Milligram		Bristol Myers Squibb
	Abatacept			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram, Cycle		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cycle		Not Reported

Test Positive	Hydroxychloroquine Sulfate		S	Unknown	5 Milligram	Not Reported
	Leflunomide		S	Oral	10 Milligram	Not Reported
	Leflunomide		S	Oral	5 Milligram	Not Reported
	Methotrexate		S	Unknown	5 Milligram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Prednisone		C	Unknown	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	16694396	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-076882		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn E			S	Unknown	500 Milligram, Bid		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown	5 Milligram	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Lovastatin	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	50 Milligram	Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen Sodium	C	Unknown	1000 Milligram	Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Rosuvastatin	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	16720491	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2889490-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Form Of Administration-Solution, Single Use Pre-Filled Syringe		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Plaquenil	S	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Folic Acid	C	Oral		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	17901272	EXPEDITED (15-DAY)		OT	NVSC2020ES164416		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina			S	Oral	500 Mg, Q24h		Not Reported
	Azitromicina			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Novartis
	Hydroxychloroquine			S				Novartis
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxona			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	2 Df, Unknown (Total)		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	17981077	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052702			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Azithromycin			S	Unknown	500 Milligram		Zydus Pharm
	Metilprednisolona [Methylprednisolone]			S	Unknown	40 Milligram		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form		Not Reported
	Dolquine			S	Oral	200 Milligram		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not	2 Gram		Not Reported

			otherwise specified)		
	Metamizol [Metamizole]	C	Unknown	Unk	Not Reported
	Clexane	C	Unknown		Not Reported
	Omeprazole	C	Unknown		Not Reported
	Metoclopramida [Metoclopramide]	C	Unknown		Not Reported
	Paracetamol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	17981361	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796225		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Fentanyl			S	Unknown			Cephalon
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2.5 Milligram Daily;		Not Reported
	Celebrex			S	Oral			Not Reported
	Nasonex			C				Not Reported
	Prednisone			C				Not Reported
	Trazodone			C				Not Reported
	Tylenol			C				Not Reported
	Zoledronic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	11108701	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015045489		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk (1 Every 2 Week)		Amgen
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, (1 Every 1 Week)		Not Reported
	Methotrexate			S	Unknown	15 Milligram , (1 Every 1 Week)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qwk (1 Every 1 Week)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid (2 Every 1 Day)		Not Reported
	Anakinra			S	Unknown	Unk Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram (1 Every 6 Weeks)		Not Reported

Methotrexate Sodium	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Azathioprine	S	Unknown	Unk		Not Reported
Kineret	S	Subcutaneous	100 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	11191401	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015056272		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	50 Milligram, Qwk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Orencia			S	Unknown	250 Milligram		Not Reported

Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia	S	Subcutaneous	250 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	2.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	20 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	2.5 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	300 Milligram	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	2 Gram, Qd	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	2 Milligram	Not Reported
	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported

Actemra	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	11398119	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014106314		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 4 Times/Wk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, 4 Times/Wk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12147335	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016026213		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Finger Deformity; Hepatic Enzyme Increased; Hepatic Fibrosis; Hypertension; Injection Site Erythema; Insomnia; Lower Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Pain; Rash; Seronegative Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Visual Impairment	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Oral	150 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	150 Milligram, Qd		Not Reported
	Reactine			C	Unknown	10 Milligram, Qd		Not Reported
	Effexor			C	Oral	150 Milligram, Qd		Not Reported
	Cetirizine			C		10 Milligram, Qd		Not Reported
	Ultram			C	Unknown	Unk, Q4h		Not Reported
	Zopiclone			C	Unknown	7.5 Milligram, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12299427	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016051438		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Intolerance; Nausea; Off Label Use; Prescribed Overdose; Prescribed Underdose	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Naprosyn	S	Unknown	500 Mg, Bid	Not Reported
	Orencia	S	Subcutaneous	150 Mg, Qmo	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Qd	Not Reported
	Naproxen	S	Unknown	500 Milligram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12470396	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016074646		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	4 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported

Orencia	S	Intravenous (not otherwise specified)	750 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1 Gram	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Unknown	20 Milligram	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1 Gram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	300 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Leflunomide	C	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	C	Unknown	20 Milligram, Qd	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported

Tocilizumab	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	0.8 Milliliter, Qwk		Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qwk		Not Reported
Methotrexate	C	Oral	Unk, Qwk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Diclofenac	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Valsartan	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12612693	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015128883		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12650430	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016089419		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology	Enbrel			S	Unknown	Unk		Amgen

Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Gold	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Qwk	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	11.2 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q12h	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd	Not Reported
	Prednisone	C	Unknown	15 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	15 Milligram, Bid	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12675144	NON-EXPEDITED		OT	CA-AMGEN-CANSL2015044183		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Remicade			C	Intravenous (not	Unk		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12676434	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016108897		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Apo Celecoxib			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydromorphone	C		Unk		Not Reported
Hydromorphone	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12678745	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016109206		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	Unk		Amgen
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	12685066	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016109223		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	100 Milligram		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

					otherwise specified)					
	Leflunomide			C	Unknown	Unk				Not Reported
	Leflunomide			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	13158932	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005744		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	25.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Oral	25.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram, 1 Every 1 Day		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral	10 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

Plaquenil [Hydroxychloroquine Phosphate]	S	Oral			Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Bid		Not Reported
Leflunomide	S	Unknown	10 Milligram		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Prednisone	C	Oral	5 Milligram, Qd		Not Reported
Prednisone	C	Oral	50 Mg, Qd		Not Reported
Xeljanz	C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	13297135	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016112986		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Plaquenil			C		200 Mg And 20 Mg, Qd		Not Reported
	Prednisone			C		3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	13594477	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017081646		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Psoriatic Arthropathy; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single Use Prefilled Syringe)		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q6wk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	400 Mg, (Q 0, 2, 6 Weeks, Then Every 8 Weeks)		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	13761472	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017105360		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen

	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Celebrex	C		Unk, As Necessary	Not Reported
	Xeljanz	C		Unk	Not Reported
	Prednisone	C		Unk Unk, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	13926256	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017375036		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Weekly		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic (Q2wk)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2x/Day		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14187136	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017170029		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone	Enbrel			S	Subcutaneous	Unk		Amgen

Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk, Bid	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14216870	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017174939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Mobicox	S	Oral	7.5 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Sulfasalazine	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14222286	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175431			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14226285	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017503742		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, Bid		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14539306	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0138		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; No Adverse Event; Renal Impairment; Therapeutic Product Effect Incomplete	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo Hydroxychloroquine			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14632234	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016103661		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Unknown
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qwk)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk, (Therapy Duration: 730.0)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

Apo-Leflunomide	S	Unknown	Unk		Not Reported
Arava	C		Unk		Not Reported
Sodium Aurothiomalate	C		Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, 2x/Day		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported
Gold	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14635302	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018104199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	14637077	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018106239			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15250694	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015389147		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Pain; Peripheral Swelling; Rash; Swelling; Treatment Failure; Urticaria	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rocuronium Bromide			S	Unknown	Unk		Pfizer
	Rocuronium Bromide			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Sulfamethoxazole W/Trimethoprim		S	Unknown	Unk	Not Reported
	Penicillin		S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate		S	Parenteral	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15504213	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015057703		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	40 Milligram, Q2wk		Amgen
	Methotrexate			S	Oral	Unk, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Apo-Azathioprine	S	Unknown	Unk		Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk		Not Reported
Methotrexate Sodium	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Prednisone	C		Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15663999	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570464-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Itravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Ntravenous		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rituximab	S		Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15668473	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570151-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Off Label Use; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported

	Restasis	C	Not Reported
	Synthroid	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15697307	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2055186-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Cyclosporine			S	Oral			Not Reported
	Cyclosporine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Cyclosporine	S	Oral	Not Reported
	Lyrica	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported
	Piroxicam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15702741	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580894-00		54 YR	Female	CAN

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

	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Arthrotec	C	Oral	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15734387	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594151-00		65 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15803741	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2618078-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15878444	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019012819		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

Failure	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	25 Mg, Qwk	Not Reported
	Prednisone	C	Unknown	30 Mg, Qd	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15923113	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653533-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Mobicox	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15935383	EXPEDITED (15-DAY)		LT, OT	CA-ABBVIE-19K-028-2656801-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration-5 Month		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Kevzara	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	15935646	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2657083-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Ciclosporin	C	Not Reported
	Prednisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	16201898	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019058114			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	16201961	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019057998		59 YR	Male	CAN

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

Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Enbrel	S	Subcutaneous	50 Milligram	Amgen
	Enbrel	S	Subcutaneous	50 Milligram	Amgen
	Enbrel	S	Subcutaneous	50 Milligram	Amgen
	Enbrel	S	Subcutaneous	50 Milligram	Amgen
	Mesalazine	S	Oral	800 Milligram , 3 Every One Day	Not Reported
	Amlodipine Besylate	S	Oral	5 Milligram, Qd	Not Reported
	Amlodipine Besylate	S	Oral	Unk Unk, Qd	Not Reported
	Amlodipine Besylate	S	Unknown	Unk	Not Reported
	Asacol	S	Unknown	800 Milligram, Tid (Tablet (Enteric Coated))	Not Reported
	Diamicron	S	Unknown	Unk	Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Crestor	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported

	Ebastine	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Tylenol [Paracetamol]	C		500 Milligram	Not Reported
	Vitamin D3	C		1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	16772606	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2909488-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Synthroid			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Asa			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Tylenol			S	Unknown	Prn Frequency		Not Reported
	Tylenol			S	Unknown	600 (No Unit)		Not Reported
	Vitamin D			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Colecalciferol			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17605717	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332773		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Morphine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17716579	EXPEDITED (15-DAY)		HO, OT	MX-ADVANZ PHARMA-202004004174			Unknown	MEX

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

Renal Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17744165	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436847		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported

	Rituximab	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Lyrica	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17744167	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200436843		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Alopecia; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Nausea; Neoplasm Malignant; Neutropenia; Onychoclasis; Osteoarthritis; Synovitis; Tachycardia; Tooth Loss; Type 2 Diabetes Mellitus; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not			Not Reported

			otherwise specified)		
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Zostavax Ii	S	Subcutaneous		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C			Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Cortisone Acetate	C	Subcutaneous		Not Reported
	Desoximetasone	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17772547	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK202004490		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome; Product Use In Unapproved Indication	Midazolam (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Midazolam (Manufacturer Unknown)			S				Fresenius Medical Care
	Propofol (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Propofol (Manufacturer Unknown)			S				Fresenius Medical Care
	Ceftriaxon (Manufacturer Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	A Compressed Breakfast And Dinner		Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Zea Mays Extract			C	Unknown			Not Reported
	Formoterol Fumarate/Budesonide			C	Unknown			Not Reported
	Tamsulosin Hydrochloride			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported

	Hydrocortisone Acetate			C	Unknown					Not Reported
	Verapamil Hydrochloride			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17875794	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609668		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17898073	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-250385		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash	Azithromycin			S	Oral	500 Milligram, Daily		Sun

	Roactemra 20 Mg/Ml Concentrate For Solution For Infusion	S	Unknown	1 Dosage Form, Daily	Not Reported
	Clexane	S	Subcutaneous	8000 Kilo-International Unit, Daily	Not Reported
	Plaquenil	S	Oral	2 Dosage Form, Daily	Not Reported
	Fidato 2 G Polvere Per Soluzione Per Infusione	S	Intravenous (not otherwise specified)	1 Dosage Form, Daily	Not Reported
	Urbason Solubile	S	Intravenous (not otherwise specified)	1 Dosage Form, Daily	Not Reported
	Kaletra	S	Oral	4 Dosage Form, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17907319	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1055888		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Neutropenia; Off Label Use; Thrombocytopenia	Bisoprolol			S		Unk		Not Reported
	Paroxetine			S		Unk		Not Reported
	Furosemide			S		Unk		Not Reported
	Atorvastatin			S		Unk		Not Reported
	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Azithromycin			S		500 Milligram		Not Reported
	Amiodarone			S		Unk		Not Reported
	Enoxaparin			S		Unk		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram		Mylan
	Plaquenil /00072603/			S	Oral	200 Mg, Qd		Mylan
	Sarilumab			S	Subcutaneous	400 Milligram, Total (400 Mg, 1x)		Mylan
	Levothyroxine			C		Unk		Mylan
	Lansoprazole			C		Unk		Mylan
	Gabapentin			C		Unk		Mylan

Racecadotril	C	Unk	Mylan
Tamsulosin	C	Unk	Mylan
Amlor	C	Unk	Mylan
Seresta	C	Unk	Mylan
Clopidogrel	C	Unk	Mylan
Eplerenone	C	Unk	Mylan
Alprazolam	C	Unk	Mylan
Kcl	C	Unk	Mylan
Hydroxyzine /00058402/	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17925866	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200624090		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17925873	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200624094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis; X-Ray Abnormal	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17939882	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200624093		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil /00072603/	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17975286	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052254			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Remicade			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17979623	EXPEDITED (15-DAY)		HO	NVSC2020IT185911		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash; Rash	Levofloxacin			S	Oral	1 Df, Qd		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17981584	EXPEDITED (15-DAY)		HO, LT, OT	BE-AUROBINDO-AUR-APL-2020-031948		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemolysis; Off Label Use; Renal Ischaemia; Toxicity To Various Agents	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17981744	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127692		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Qmo	Not Reported
Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo	Not Reported
Venlafaxine Hydrochloride	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17981753	EXPEDITED (15-DAY)		OT	CA-ACCORD-188258			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Off Label Use; Polyarthritis; Skin Lesion; Treatment Failure;	Methotrexate			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported

Uveitis	Adalimumab	S	Unknown	Solution Subcutaneous		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Infliximab	S	Unknown	Powder For Solution Intravenous		Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17981790	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982196	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-033460		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat Irritation	Azithromycin			S	Unknown	1000 Mg / 1 Day And 500 Mg Rest		Aurobindo
	Clarithromycin			S	Unknown	50 Milligram, Once A Day		Aurobindo

	Dolquine	S	400 Milligram, Once A Day		Not Reported
	Kaletra	S	800 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982215	EXPEDITED (15-DAY)		LT	NVSC2020ES188358		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Novartis
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported
	Rezolsta			S	Oral	1 Df, Qd		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	1000 Mg, Qd		Not Reported
	Kaletra			C	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982243	EXPEDITED (15-DAY)		OT	PL-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-252356		35 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Meropenem			S	Intravenous (not otherwise specified)	1 Gram, Qd		Not Reported
	Azithromycin			S	Unknown	500 Milligram, Qd		Sun
	Hydroxychloroquine			S	Unknown	250 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982475	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053069		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Drug Ineffective; Fall; Fatigue;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Apo-Leflunomide		S	Unknown		Not Reported
	Apo-Naproxen		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Not Reported
	Leflunomide		S	Oral		Not Reported
	Naproxen Sodium		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982557	EXPEDITED (15-DAY)		HO, OT	LT-ORION CORPORATION ORION PHARMA-TREX2020-2240		55 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Osteoporosis; Pancytopenia; Tick-Borne Viral Encephalitis	Methotrexate			S	Unknown	Dose Was Increased To 15 Mg Per Week		Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown	Decreased Dose		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Lornoxicam			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Verapamil-Trandolapril			S	Unknown	Dose: 240mg/4mg		Not Reported
	Infliximab			S	Unknown	Two Courses		Not Reported
	Ceftazidime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982625	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020106556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown			Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982695	EXPEDITED (15-DAY)		OT	CA-ACCORD-188680		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982703	EXPEDITED (15-DAY)		OT	CA-ACCORD-188710		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Ineffective; Platelet Count Decreased; Product Use Issue; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Salazopyrin			C				Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982709	EXPEDITED (15-DAY)		OT	CA-ACCORD-188709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Methotrexate			S	Intravenous (not otherwise specified)			Accord
	Arava			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Breo Ellipta			S	Respiratory (inhalation)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Colchicine			S				Not Reported
	Dexilant			S	Oral	1 Every 1 Days		Not Reported
	Estrogel			S	Topical	1 Every 1 Days		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Plaquenil			S	Unknown	2 Every 1 Days		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ventolin Hfa			S	Respiratory	Metered Dose		Not Reported

	Methotrexate		S	(inhalation) Oral	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982731	EXPEDITED (15-DAY)		OT	CA-ACCORD-188176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Spinal Column Injury; Treatment Failure	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982732	EXPEDITED (15-DAY)		OT	CA-ACCORD-188177			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Calcium Carbonate			S	Oral			Not Reported
	Celecoxib			S	Unknown	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Magnesium Aspartate			C	Oral			Not Reported
	Fish Oil			C	Unknown			Not Reported

	Prednisone		S	Unknown	1 Every 1 Days	Not Reported
	Nabumetone		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982743	EXPEDITED (15-DAY)		OT	CA-ACCORD-188178			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Codeine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Arava			C	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982794	EXPEDITED (15-DAY)		OT	CA-ACCORD-188549			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Enbrel			S				Not Reported
	Etanercept			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982798	EXPEDITED (15-DAY)		OT	CA-ACCORD-188273		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug	Methotrexate			S				Not Reported

Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Enbrel	S				Not Reported
	Hydroxychloroquine	S				Not Reported
	Leflunomide	S				Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	2 Every 1 Days		Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982819	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796315		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	200 Milligram Daily;		Actavis
	Fentanyl			S	Unknown			Cephalon
	Fentanyl			S	Unknown			Cephalon
	Celecoxib			S	Oral			Teva
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)	16 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram Daily;		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Diphenoxylate Hydrochloride			C				Not Reported

	Ergocalciferol	C			Not Reported
	Esomeprazole	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Oxycodone	C	Unknown		Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C			Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17982853	EXPEDITED (15-DAY)		OT	CA-ACCORD-188556			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Polyarthritis; Skin Lesion; Uveitis	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983245	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020105942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Codeine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

	Hydroxychloroquine		S	Unknown			Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Sulfasalazine		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983507	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053315		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983552	EXPEDITED (15-DAY)		OT	CA-ACCORD-188751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983698	EXPEDITED (15-DAY)		OT	CA-ACCORD-188371			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Methotrexate			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported
	Mycophenolic Acid			C	Oral	2 Every 1 Days		Not Reported
	Metformin			C	Oral	2 Every 1 Days		Not Reported
	Lipitor			C		1 Every 1 Days		Not Reported
	Infliximab			C				Not Reported
	Glyburide			C		1 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983706	EXPEDITED (15-DAY)		HO	ES-ACCORD-188920		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use	Hydroxychloroquine			S		400 Mg/12 Hours During The First Day, Then 200 Mg/12 H During 4-9 Days		Not Reported

	Lopinavir/Ritonavir	S	200/100 Mg Twice A Day For 14 Days		Not Reported
	Everolimus	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984280	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200321038			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984394	EXPEDITED (15-DAY)		DE, LT	CA-ACCORD-188354		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S			Not Reported
	Ilaris	S			Not Reported
	Leflunomide	S			Not Reported
	Marijuana	S			Not Reported
	Minocycline/Minocycline Hydrochloride	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S			Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Lyrica	C			Not Reported
	Kineret	C			Not Reported
	Humira	S			Not Reported
	Ilaris	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984421	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796358		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal	Gabapentin			S	Oral	200 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Fentanyl			S	Unknown			Cephalon
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Oral	200 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram Daily;	Not Reported
	Acetaminophen/Oxycodone Hydrochloride	C	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Biotin	C			Not Reported
	Diphenoxylate Hydrochloride	C			Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Ferrous Fumarate	C			Not Reported
	Loperamide	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C			Not Reported
	Perphenazine	C			Not Reported
	Prednisone	C			Not Reported
	Pyridoxine	C	Unknown		Not Reported
	Retinol Palmitate	C	Unknown		Not Reported
	Riboflavin	C			Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Thiamine Mononitrate	C			Not Reported
	Thiamine Hcl	C			Not Reported
	Trazodone	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin A	C	Unknown		Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown		Not Reported
	Vitamin D3	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984456	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1060160		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Off Label Use	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Mylan
	Norepinephrine			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984819	EXPEDITED (15-DAY)		OT	NVSC2020BR188613		29 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Bid		Novartis
	Azithromycin			C	Unknown	Unk		Not Reported
	Piperacillin+Tazobactam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984922	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796362		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal	Gabapentin			S	Oral	200 Milligram Daily;		Ivax
	Methotrexate			S	Subcutaneous			Barr
	Fentanyl			S	Unknown			Cephalon
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported

Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Biotin	C			Not Reported
	Cyanocobalamin	C			Not Reported
	D-Alpha Tocopherol	C			Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole	C			Not Reported
	Ferrous Fumarate	C			Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Lomotil	C			Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Nicotinamide	C			Not Reported
	Nortriptyline	C			Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C			Not Reported
	Pyridoxine	C			Not Reported
	Retinol Palmitate	C			Not Reported
	Riboflavin	C			Not Reported
	Risedronate Sodium	C			Not Reported
	Sodium Ascorbate	C			Not Reported
	Thiamine Hydrochloride	C			Not Reported
	Trazodone	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin A	C			Not Reported
	Vitamin B1	C			Not Reported
	Vitamin C [Ascorbic Acid]	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984939	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252144		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Milligram, 1dose/12hour		Sun
	Methylprednisolone			S	Unknown	4 Milligram, Daily		Not Reported
	Nintedanib			S	Unknown	150 Milligram, 1dose/12hour		Not Reported
	Nintedanib			S	Unknown	100 Milligram, 1dose/12hour		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984960	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252324		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Hyperkalaemia	Hydroxychloroquine			S	Unknown	2000 Milligram, Bid		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984965	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796348			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Gabapentin			S	Oral	200 Milligram Daily;		Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported

Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Celebrex	S	Occlusive dressing technique		Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;	Not Reported
	Vitamin B1 Thiamine - 100 Mg	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Aclasta	C	Unknown		Not Reported
	Ascorbic Acid	C	Unknown		Not Reported
	Biotin	C	Unknown		Not Reported
	Cholecalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Ferrous Fumarate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Lomotil	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Nasonex	C	Unknown		Not Reported
	Nicotinamide	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Retinol Palmitate	C	Unknown		Not Reported
	Riboflavin	C	Unknown		Not Reported

	Risedronate Sodium			C	Unknown					Not Reported
	Thiamine Hydrochloride			C	Unknown					Not Reported
	Trazodone			C	Unknown					Not Reported
	Tylenol			C	Unknown					Not Reported
	Vitamin A			C	Unknown					Not Reported
	Vitamin B6			C	Unknown					Not Reported
	Vitamin C [Ascorbic Acid]			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985147	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0788		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985222	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Rituximab			S	Endocervical	Unk		Not Reported
	Simponi			S	Subcutaneous	3 Milligram/Kilogram		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985230	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053356			Female	CAN

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

Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported
	Cimzia	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985256	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA3367		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Anakinra			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Bumetanide			S	Unknown			Not Reported
	Capsaicin			S	Topical			Not Reported
	Cimetidine			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Diltiazem			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Ibudilast	S	Unknown		Not Reported
Ketamine	S	Topical		Not Reported
Ketamine	S	Oral		Not Reported
Ketamine	S	Intravenous (not otherwise specified)		Not Reported
Lidocaine	S	Topical		Not Reported
Lidocaine	S	Intravenous (not otherwise specified)		Not Reported
Lithium Carbonate	S	Unknown		Not Reported
Magnesium	S	Unknown		Not Reported
Magnesium	S			Not Reported
Memantine	S	Unknown		Not Reported
Metprolol	S	Unknown		Not Reported
Mexiletine	S	Unknown		Not Reported
Montelukast	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
N-Acetylcysteine	S	Unknown		Not Reported
Naltrexone Hydrochloride	S	Unknown	4.5 Mg	Not Reported
Palmitoylethanolamide	S	Unknown		Not Reported
Pentoxifylline	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown	5 Mg	Not Reported
Prednisone	S	Unknown	13 Mg	Not Reported
Pregabalin	S	Unknown		Not Reported
Spironolactone	S	Unknown		Not Reported
Vitamin B2	S	Unknown		Not Reported
Vitamin B2	S			Not Reported

	Vitamin C	S	Unknown	Not Reported
	Calcitonin	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Ezetimibe	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985271	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052989		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985399	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053066			Female	CAN

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

Cetrizine	S	Unknown	10 Milligram		Not Reported
Cimzia	S	Subcutaneous			Not Reported
Cortisone Acetate	S	Unknown			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Folic Acid	S	Unknown	5 Milligram		Not Reported
Fosamax	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Apo-Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985422	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Abatacept			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Q4wk		Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	200 Milligram		Not Reported
Synthroid	C	Unknown			Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985451	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020106022		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985546	EXPEDITED (15-DAY)		OT	NVSC2020ES188439		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Hydroxychloroquine			S	Oral	1 Df, Q12h		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Azithromycin			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Df, Q12h		Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985786	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053499		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported

	Perindopril	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Qid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985953	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2020ES188262		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrial Fibrillation; Cardiac Failure; Death; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Respiratory Failure	Azithromycin			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Novartis
	Azithromycin			S				Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methylprednisolone Acetate			S	Unknown	Lower Doses (+/- 1mg/Kg Per Day)		Not Reported
	Methylprednisolone Acetate			S				Not Reported
	Methylprednisolone Acetate			S				Not Reported
	Lopinavir + Ritonavir			S	Unknown	Unk		Not Reported
	Lopinavir + Ritonavir			S				Not Reported
	Lopinavir + Ritonavir			S				Not Reported
	Ertapenem Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985968	EXPEDITED (15-DAY)		LT	NVSC2020ES188270		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azitromicina			S	Unknown	Unk		Novartis
	Dolquine			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17986207	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019216530		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Enbrel			S		Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Kineret			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Azathioprine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17986214	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020257928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate	Enbrel			S		Unk		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day (Bid)		Pfizer
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg		Not Reported

Abnormal; Synovitis	Leflunomide	S		Unk	Not Reported
	Naproxen	S		Unk	Not Reported
	Naproxen Sodium	S	Oral	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Hydroxychloroquine Sulfate	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	10614679	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1496772		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Actemra			S	Intravenous (not otherwise specified)	Started Summer 2013, Had 3 Doses In Total		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown	2009 Or 2012 Start, Stopped Fall 2014. Later Re-Started It Again.		Not Reported
	Celebrex			S	Unknown	Re-Started When Had A Rheumatoid Arthritis Flare		Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	6 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Stopped As Did Not Do Anything		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Dilaudid	C	Unknown	As Needed, Started 2009 Approximately	Not Reported
	Dilaudid	C	Unknown	As Required	Not Reported
	Lyrica	C	Oral	2 Capsules Morning, 1 At Night, 2010 Start Approx.	Not Reported
	Hydromorph Contin	C	Unknown		Not Reported
	Hydromorph Contin	C	Unknown	Sustained Release	Not Reported
	Furosemide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	11173619	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1589861		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapy Non-Responder; Therapy Non-Responder	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cimzia	S	Unknown	Therapy Duration: 305 Days	Not Reported
	Cimzia	S	Unknown	Therapy Duration: 10.0 Month	Not Reported
	Cimzia	S	Unknown	Single Use Pre-Filled Syringe	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown	5-20 Mg As Necessary	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	11290381	EXPEDITED (15-DAY)		OT	CA-ROCHE-1610671		75 YR	Female	CAN

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

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years	Not Reported
	Rituxan	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 3 Years, Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 1 Year	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown	Therapy Duration: 9 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 730 Days	Not Reported
	Arava	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

Methotrexate	S	Unknown	11.0 Years	Not Reported
Methotrexate	S	Unknown	Therapy Duration: 4015.0 Days	Not Reported
Methotrexate	S	Vaginal		Not Reported
Methotrexate	S	Unknown		Not Reported
Ativan	C	Unknown		Not Reported
Cortisone	C	Intramuscular		Not Reported
Cortisone	C	Intra-articular		Not Reported
Cortisone	C	Oral		Not Reported
Darifenacin	C	Unknown	As Required	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	As Required	Not Reported
Furosemide	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray, Metered Dose	Not Reported
Pantoprazole Sodium	C			Not Reported
Synthroid	C			Not Reported
Vagifem	C	Vaginal	Vaginal Tablet	Not Reported
Vagifem	C	Unknown		Not Reported
Anakinra	C			Not Reported
Abatacept	C			Not Reported
Leflunomide	C	Unknown		Not Reported
Lasix [Furosemide]	C	Unknown		Not Reported
Lasix [Furosemide]	C	Unknown		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Tablet (Extended Release)	Not Reported

Enablex [Darifenacin Hydrobromide]	C	Unknown			Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Tablet (Enteric Coated)		Not Reported
Urispas	C	Unknown			Not Reported
Triamcinolone Acetonide	C	Intra-articular			Not Reported
Trimethoprim	C	Unknown			Not Reported
Restasis	C	Unknown			Not Reported
Plantago Ovata	C	Unknown			Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown			Not Reported
Pantoprazole	C				Not Reported
Oxyneo	C	Unknown			Not Reported
Orphenadrine Hydrochloride	C	Unknown	1.0 Dosage Forms		Not Reported
Morphine Sulfate	C	Unknown			Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular			Not Reported
Kineret	C	Unknown			Not Reported
Kadian	C	Unknown			Not Reported
Hydromorphone	C	Unknown			Not Reported
Dyclone	C				Not Reported
Desoximetasone	C	Oral			Not Reported
Desoximetasone	C	Unknown			Not Reported
Desoximetasone	C	Intramuscular			Not Reported
Diphenhydramine	C				Not Reported
Darifenacin Hydrobromide	C	Unknown			Not Reported
Codeine	C				Not Reported
Acetaminophen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	11801930	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015411810		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance;	Enbrel			S	Subcutaneous	Unk		Pfizer

Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk		Pfizer
	Sulfasalazine	S		500 Mg X 2, Unk		Pfizer
	Sulfasalazine	S		1 G, 2x/Day		Pfizer
	Sulfasalazine	S		500 Mg X 2, Unk		Pfizer
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	12313620	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016231208		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Overdose; Prescribed Underdose	Enbrel			S	Subcutaneous	50 Mg, Unk		Unknown
	Celebrex			S	Unknown	200 Mg, Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Qd		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Pfizer
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Bid		Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Bid		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Qmo		Not Reported

Orencia	S	Subcutaneous	150 Mg, Qmo		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
Simponi	S	Subcutaneous	50 Mg, Qmo		Not Reported
Simponi	S	Subcutaneous	50 Mg, Monthly		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd		Not Reported
Apo-Hydroxyquine	S	Unknown	400 Mg, Qd		Not Reported
Apo-Hydroxyquine	S	Unknown	400 Mg, Qd		Not Reported
Naproxen	S	Unknown	500 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	12659993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016335872		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, Qd		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported

	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	11.2 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day(Bid)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	15 Milligram, Qd (Daily)	Not Reported
	Prednisone	C	Unknown	15 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	12681997	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016400589		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5.0 Milligram, Bid		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported

Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	10 Mg/Kg, Weekly		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk (Powder For Solution)		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Apo Celecoxib	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Prednisone	C	Unknown	2 Mg, 1x/Day		Not Reported
Hydromorphone	C	Unknown	Unk		Not Reported
Hydromorphone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	12703204	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016404361		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Oral	500 Mg, 1x/Day(Daily)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Daily		Not Reported

Leflunomide	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day		Not Reported
Prednisone	C	Unknown	3 Mg, 1x/Day(Daily)		Not Reported
Plaquenil	C		200 Mg, 1x/Day(Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	12712380	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016130276		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Finger Deformity; Hepatic Enzyme Increased; Hepatic Fibrosis; Injection Site Erythema; Insomnia; Lower Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Pain; Rash; Swelling; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Effexor Xr			S	Oral	150 Mg, 1x/Day		Pfizer
	Venlafaxine Hcl			S	Oral	150 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligrams, Bid		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Mg, 1x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Reactine			C	Unknown	10 Mg, 1x/Day		Not Reported
	Cetirizine			C		10 Milligram, Qd		Not Reported
	Ultram [Tramadol Hydrochloride]			C	Unknown	Unk, Q4h		Not Reported
	Zopiclone			C	Unknown	7.5 Milligram, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	12939528	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016521754		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 Milligram, Unk (For 8 Years)		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Diclofenac Sodium/Misoprostol			S	Unknown	50 Mg, Bid		Pfizer
	Diclofenac Sodium/Misoprostol			S	Unknown	7.5 Milligram, Bid		Pfizer
	Diclofenac Sodium/Misoprostol			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (For 8 Years)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		For 8 Years	Not Reported
	Vitamin D	C		Unk	Not Reported
	Arthrotec	C	Unknown	50 Mg, 2 Every 1 Day	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	C	Unknown	Unk	Not Reported
	Gold	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	13063060	EXPEDITED (15-DAY)		OT	CA-ROCHE-1631753			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Liver	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Not Controlling Disease And Causing Debilitation And Inability To Perform		Not Reported

Injury; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Daily Activities Didn'T Work And Patient Still Symptomatic	Not Reported
	Leflunomide		S	Unknown	Didn'T Work And Patient Still Symptomatic	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Affected Liver Enzymes	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	13166337	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017014736		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Q12h		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q12h	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd	Not Reported
	Lyrica	C	Oral	50 Mg Am And 100 Mg Hs	Not Reported
	Lyrica	C		Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	13299527	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016375688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Unknown	Unk		Unknown
	Celecoxib			S	Oral	200 Mg, Bid		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Actemra	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Oral	200 Mg, Bid	Not Reported
	Apo Celecoxib	S	Oral	200 Mg, 2x/Day	Not Reported
	Toradol	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	7-10 Milligram, Unk	Not Reported
	Tramadol	C	Unknown	100 Mg, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	13816053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017329621		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Df, Weekly (1 Dosage Form, Qwk)		Pfizer
	Enbrel			S		Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

Prednisone	C	Oral	Unk		Not Reported
Prednisone	C		Unk		Not Reported
Arava	C		Unk		Not Reported
Codeine	C		Unk		Not Reported
Tylenol [Paracetamol]	C		Unk		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Lyrica	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	13864958	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015286770		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Milligram 1 Every 12 Hours		Pfizer
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	50 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported

Actemra	S	Unknown	8 Milligram/Kilogram, Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk (7 Years)	Not Reported
Orencia	S	Unknown	750 Milligram, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	500 Mg, Unk (9 Months)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid (5 Months)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Bid	Not Reported
Simponi	S	Subcutaneous	50 Mg, Unk (3 Years)	Not Reported
Simponi	S	Subcutaneous	50 Mg, Unk	Not Reported
Leflunomide	S		Unk	Not Reported
Apo-Prednisone	S	Oral	Unk Unk, Qd	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	14226677	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017507919			Female	CAN

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

Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Enbrel	S	Subcutaneous	Unk	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, 1x/Day	Pfizer
	Methotrexate Sodium	S		15 Mg, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	1 G, 1x/Day	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	14227055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mobicox			S	Oral	7.5 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	14646706	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15464129	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016330709		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	50 Milligram, Qwk		Pfizer
	Codeine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous	400 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15556623	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018148882		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	200 Milligram,2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram, Once Every 2 Weeks		Not Reported
	Xeljanz			C		5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15556949	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015270940		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Swelling; Therapeutic Product Effect Incomplete;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Qweek		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Rituximab			S	Unknown			Pfizer

Therapy Non-Responder	Actemra	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported
	Rituxan	S		Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15605068	EXPEDITED (15-DAY)		OT	PT-ACCORD-091178		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Haemophagocytic Lymphohistiocytosis; Herpes Zoster; Listeria Sepsis; Lymphopenia; Off Label Use; Progressive Multifocal Leukoencephalopathy	Methotrexate			S		Not Provided		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown	Not Provided		Not Reported
	Azathioprine			S	Unknown	Not Provided		Not Reported
	Thalidomide			S	Oral	Not Provided		Not Reported
	Hydroxychloroquine			S	Unknown	Not Provided		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Not Provided		Not Reported
	Cellcept			S	Oral			Not Reported
	Thalidomide Celgene			C	Oral			Not Reported
	Methotrexate			S	Oral	Not Provided		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15620153	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555991-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Marijuana			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15622004	EXPEDITED (15-DAY)		CA, OT	CA-ABBVIE-18K-028-2557160-00			Male	CAN

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

Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15670302	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2571378-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S			Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Leflunomide	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Tylenol	C	Unknown		Not Reported
Advil	C			Not Reported
Dequalinium Chloride	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15679987	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2573622-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Increased; Wheelchair User	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Statex [Morphine Sulfate]	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Statex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15713147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588025-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15733751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594183-00		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15922651	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653466-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15923150	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2653452-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Arthritis; Sciatica; Treatment Failure	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Dorzolamide Hydrochloride	S	Ophthalmic	Not Reported
	Timolol Maleate	S	Ophthalmic	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Levothyroxine Sodium	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Ramipril	S	Oral	Not Reported
	Caffeine	C	Unknown	Not Reported
	Codeine Phosphate	C	Unknown	Not Reported
	Meprobamate	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Tylenol	C		Not Reported
	Dihydrocodeine	C	Unknown	Not Reported
	Acetaminophen W/Caffeine	C		Not Reported
	Diphenhydramine	C		Not Reported
	Methylprednisolone	C		Not Reported
	Tylenol With Codeine	C		Not Reported
	Acetaminophen And Codeine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	15936329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657755-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Bp		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	16207344	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Plaquenil	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Naproxen	C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	16209335	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167731		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Enbrel			S	Subcutaneous	50 Milligram		Unknown
	Enbrel			S	Subcutaneous	50 Milligram		Unknown
	Enbrel			S	Subcutaneous	50 Milligram		Unknown
	Enbrel			S	Subcutaneous	50 Milligram		Unknown
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Pfizer
	Amlodipine Besilate			S	Oral	Unk Unk, Qd		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Asacol			S	Unknown	800 Milligram, Tid (Tablet (Enteric Coated))		Not Reported
	Diamicron			S		Unk		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Mesalazine	S	Oral	800 Milligram , 3 Every One Day	Not Reported
Acetaminophen	C	Oral	650 Milligram	Not Reported
Atacand Plus	C	Oral	Unk, Qd	Not Reported
Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
Crestor	C		Unk	Not Reported
Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Ebastine	C		Unk	Not Reported
Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
Folic Acid	C	Oral	5 Milligram	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Tylenol [Paracetamol]	C		500 Milligram	Not Reported
Vitamin D3	C		1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	6342875	EXPEDITED (15-DAY)		HO	GXKR2007ES04892		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactate Dehydrogenase Increased; Hepatic Enzyme Increased; Hepatitis Acute; Nausea; Pyrexia; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg/Day		Novartis
	Hydroxychloroquine			S				Novartis
	Prednisone			C	Unknown	40 Mg/Day		Not Reported
	Nsaid'S			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	16411506	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016400783		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	16439059	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018011428		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Actemra	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	10 Milligram, 1x/Day	Not Reported
Leflunomide	S	Unknown	10 Milligram, 1x/Day	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

Arava	C	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous	Unk		Not Reported
Simponi	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Bupropion	C		Unk		Not Reported
Sulfasalazine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	16793789	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018056893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	15 Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Orencia	S	Subcutaneous	125 Milligram, Unk	Not Reported
Orencia	S	Subcutaneous	125 Milligram, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Unknown	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Unknown	50 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cosentyx	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	16827323	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2930035-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Tylenol			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported
	Synthroid			C				Not Reported
	Meloxicam			C				Not Reported

	Acetaminophen And Codeine	C	Not Reported
	Codeine Phosphate	C	Not Reported
	Methotrexate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17224878	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-3214954-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Tramacet			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Acetaminophen			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Nortriptyline Hydrochloride			C				Not Reported
	Ergocalciferol			C				Not Reported
	Vagifem			C	Vaginal			Not Reported
	Tylenol			C				Not Reported
	Premarin			C		0.625 Milligram		Not Reported

	Nortriptyline	C		Not Reported
	Nortriptyline	C		Not Reported
	Methylprednisolone Acetate	C	Intramuscular	Not Reported
	Methylprednisolone Acetate	C		Not Reported
	Methylprednisolone Acetate	C		Not Reported
	Metformin	C		Not Reported
	Lyrica	C	Oral	Not Reported
	Lorazepam	C		Not Reported
	Calcium Carbonate	C		Not Reported
	Risedronate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17233169	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17250075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516466		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S				Not Reported

	Leflunomide	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Methotrexate Sodium	C	Subcutaneous	Not Reported
	Methotrexate Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17588061	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020126107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17708221	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002358			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Off Label Use; Pneumonia; Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	800 Mg, Qd		Concordia
	Enoxaparin			C		Unk		Not Reported
	Enoxaparin			C				Not Reported
	Paracetamol			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Celocurine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17814839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598481		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Off Label Use; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17880158	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17954776	EXPEDITED (15-DAY)		HO	BR-ADVANZ PHARMA-202006006752			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd, Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Allopurinol			C		Unk		Not Reported
	Arthromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Sertraline			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Levothyroxine Sodium			C		Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Formoterol			C		Unk		Not Reported
	Budesonide			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Methylprednisolone Sodium Succinate			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Tiotropium			C		Unk		Not Reported
	Dimenhydrinrate 50mg+Vitamin B6			C	Oral	2 Capsules Per Day		Not Reported
	Sodium Dipyrone			C		1g Ampoule 2ml		Not Reported

Bolus Sodium Dipyrone	C	4g	Not Reported
Pyeroweniorodine Sulfate	C	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17965501	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-050132			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Suspension		Bristol Myers Squibb
	Triamcinolone Acetonide			S				Bristol Myers Squibb
	Triamcinolone			S	Subcutaneous	25 Milligram, Q2wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	Tablet 5 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram, Qd		Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17966606	EXPEDITED (15-DAY)		OT	GT-ADVANZ PHARMA-202006006785			Unknown	GTM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Feeling Abnormal; Intentional Product Misuse; Skin Lesion; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk, Qd		Concordia
	Aprovel			S	Unknown	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17985852	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3466962-00		65 YR	Female	CAN

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

	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17986181	EXPEDITED (15-DAY)		CA	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-052576			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Methotrexate			S	Transplacental	Unk		Zydus Pharm
	Hydroxychloroquine			S	Transplacental	Unk		Zydus Pharm
	Indomethacin			S	Transplacental	Unk		Zydus Pharm
	Leflunomide			S	Transplacental	Unk		Not Reported
	Deflazacort			S	Transplacental	Unk		Not Reported
	Chloroquine			S	Transplacental	Unk		Not Reported
	Methyldopa			S	Transplacental	Unk		Not Reported
	Hydrochlorothiazide			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17986285	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796217		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity;	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Ivax
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Celebrex	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Vaginal		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Nortriptyline	S	Oral		Not Reported
	Aclasta	C	Unknown		Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Lomotil	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Nasonex	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C			Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Perphenazine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Unknown		Not Reported
	Tylenol	C			Not Reported
	Pantoprazole Magnesium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17986530	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-252471		33 YR	Male	ITA

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

Off Label Use; Urticaria	Azithromycin		S	Oral	500 Milligram, Daily	Sun
	Plaquenil		S	Oral	400 Milligram, Daily	Not Reported
	Deltacortene 5 Mg Compresse		S	Oral	5 Milligram, Daily	Not Reported
	Cefixime		S	Oral	400 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17986998	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252297		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression	Hydroxychloroquine			S	Oral			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987054	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1796420		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Amlodipine Besilate			S	Unknown			Teva
	Amitriptyline			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Actavis
	Clonidine			S	Unknown			Actavis
	Diltiazem			S	Unknown			Teva
	Magnesium			S	Unknown			Not Reported
	Magnesium			S				Not Reported
	Memantine			S	Unknown			Teva
	Mexiletine			S	Unknown			Not Reported
	Montelukast			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Naltrexone Hydrochloride			S	Unknown	4.5 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown	95 Milligram Daily;		Actavis

Prednisone	S	Unknown		Actavis
Prednisone	S	Unknown	85 Milligram Daily;	Actavis
Prednisone	S	Unknown		Actavis
Prednisone	S	Unknown		Actavis
Pregabalin	S	Unknown		Teva
Anakinra	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Bumetanide	S	Unknown		Not Reported
Calcitonin	S	Unknown		Not Reported
Capsaicin	S	Topical		Not Reported
Cimetidine	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ibudilast	S	Unknown		Not Reported
Ketamine	S	Intravenous (not otherwise specified)		Not Reported
Ketamine	S	Topical		Not Reported
Ketamine	S	Oral		Not Reported
Lidocaine	S	Intravenous (not otherwise specified)		Not Reported
Lidocaine	S	Topical		Not Reported
Lithium Carbonate	S	Unknown		Not Reported
Metprolol	S	Unknown		Not Reported
N-Acetylcysteine	S	Unknown		Not Reported
Palmitoylethanolamide	S	Unknown		Not Reported
Pentoxifylline	S	Unknown		Not Reported
Vitamin B 2	S	Unknown		Not Reported
Vitamin B 2	S			Not Reported
Vitamin C	S	Unknown		Not Reported
Trazodone	C	Unknown		Not Reported

	Ezetimibe	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987087	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020107112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987093	EXPEDITED (15-DAY)		OT	CA-ACCORD-188439		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation	Methotrexate			S		1 Every 1 Weeks		Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Plaquenil			S		1 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		2 Every 1 Day		Not Reported

Rate Abnormal; Swelling

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987094	EXPEDITED (15-DAY)		OT	CA-ACCORD-187886		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe Dosage Form: Subcutaneous Solution		Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown	1 Every 12 Hours		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		1 Every 12 Hours		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arthrotec			C	Unknown	1 Every 12 Hours		Not Reported
	Imuran			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Colecalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Aurothioglucose			C	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987157	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1797681		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Oral			Teva
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987242	EXPEDITED (15-DAY)		HO	FR-LAURUS LABS LIMITED-202000126		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Syncope	Hydroxychloroquine			S	Oral	Three Times Per Day For Ten Days		Unknown
	Azithromycin			S	Unknown	On Day One		Not Reported
	Azithromycin			S	Unknown	On Day Two		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987247	NON-EXPEDITED			US-APPCO PHARMA LLC-2087074			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Product Substitution Issue	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987286	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Blood Cholesterol Increased;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Hypertension; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Sleep Disorder; Treatment Failure	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Day	Not Reported
	Calcium Carbonate	C	Oral	1500 Milligram, Qd	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Oral	1 Milligram	Not Reported
	Methotrexate	C	Oral	25 Milligram, Qd	Not Reported
	Naproxen	C	Unknown	500 Milligram, 2 Every 1 Day	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987347	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-052765			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pustular	Atorvastatin			S	Oral	20 Milligram, Qd		Zydus Pharm
	Furosemide			S	Oral	120 Milligram		Not Reported
	Atenolol			S	Oral	50 Milligram		Zydus Pharm
	Allopurinol			S	Oral	300 Milligram		Zydus Pharm
	Azithromycin			S	Oral	Unk		Zydus Pharm
	Lantus			S	Subcutaneous	Unk		Not Reported
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Advagraf			S	Oral	1 Dosage Form		Not Reported

Cortancyl	S	Oral	7.5 Milligram		Not Reported
Flecaine	S	Oral	100 Milligram		Not Reported
Aranesp	S	Subcutaneous	40 Microgram		Not Reported
Cholecalciferol	S	Oral	Unk		Not Reported
Plaquenil Sulfate	S	Oral	Unk		Not Reported
Loxen L P	S	Oral	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987380	EXPEDITED (15-DAY)		OT	HN-ADVANZ PHARMA-202006006899			Unknown	HND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Condition Aggravated; Ill-Defined Disorder	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987705	EXPEDITED (15-DAY)		HO, LT	CA-BAXTER-2020BAX013691		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form: Not Specified		Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Azathioprine			S	Unknown	Dosage Form: Not Specified		Not Reported
	Cellcept			S	Unknown	Dosage Form: Not Specified		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown	Dosage Form: Not Specified		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not	Dosage Form: Solution		Not Reported

			otherwise specified)	Intravenous	
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C	Unknown	Dosage Form: Not Specified	Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Methylprednisolone Sodium Succinate	C	Intravenous (not otherwise specified)		Not Reported
	Methylprednisolone Sodium Succinate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987737	NON-EXPEDITED		HO	CA-AMGEN-CANSP2020108317		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Enbrel			S	Unknown			Amgen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987767	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020106542		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987793	EXPEDITED (15-DAY)		OT	NVSC2020FR186476		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Sarilumab			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	600 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Indapamide			C	Unknown	Unk		Not Reported
	Kcl			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Lovenox			C	Unknown	Unk		Not Reported

	Cefotaxime	C	Unknown	Unk	Not Reported
	Spiramycin	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17987821	EXPEDITED (15-DAY)		OT	CA-SA-2020SA172184			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Arava			S		Unk		Sanofi
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		Unk		Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Phthalylsulfathiazole	S		400 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Diclofenac	C		Unk	Not Reported
	Salazopyrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988100	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Endocervical	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	20 Nanogram		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported

Sulfasalazine	S	Oral	1000 Milligram, Bid		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	20 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	Unk, Q4wk		Not Reported
Meloxicam Aaa	C	Unknown	Unk		Not Reported
Acetaminophen & Cod. Phosp.	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988237	EXPEDITED (15-DAY)		OT	NVSC2020ES190687		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic	Ceftriaxone			S	Unknown			Novartis
	Methylprednisolone			S	Unknown	(+/- 1 Mg/Kg Day)		Not Reported
	Tocilizumab			S	Intravenous bolus	3 Df (Bolus)		Not Reported
	Methylprednisolone			S	Intravenous bolus			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988259	EXPEDITED (15-DAY)		OT	CA-ACCORD-188752			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported

Arthritis; Therapeutic Product Effect Decreased	Infliximab		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Otezla		S	Unknown		Not Reported
	Hydromorphone		C			Not Reported
	Paracetamol		C			Not Reported
	Advair		C			Not Reported
	Allopurinol		C			Not Reported
	Atrovent Hfa		C		Metered-Dose (Aerosol)	Not Reported
	Codeine		C			Not Reported
	Cyclobenzaprine		C			Not Reported
	Dilaudid		C			Not Reported
	Esomeprazole		C			Not Reported
	Hydroxychloroquine		C			Not Reported
	Ibuprofen		C			Not Reported
	Folinic Acid		C			Not Reported
	Sulfasalazine		C			Not Reported
	Ventolin Hfa		C		Metered-Dose (Aerosol)	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988264	EXPEDITED (15-DAY)		DE, LT	CA-ACCORD-188713		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint	Methotrexate			S	Intra-arterial			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported

Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Oral		Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial	Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Xeljanz	S	Oral	1 Every 12 Hours	Not Reported
	Lyrica	C	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988378	EXPEDITED (15-DAY)		OT	CA-ACCORD-188295		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Allopurinol			C				Not Reported
	Clomipramine			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Pantoprazole			C				Not Reported

	Allopurinol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988388	EXPEDITED (15-DAY)		OT	CA-ACCORD-188179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Arava			S	Unknown	1 Every 1 Days		Not Reported
	Etanercept			S	Subcutaneous	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988398	EXPEDITED (15-DAY)		OT	ES-BAYER-2020-134478		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Interferon Beta - 1b			S	Unknown	250 Mg, Qod		Bayer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported
	Kaletra			S	Unknown	1 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988467	EXPEDITED (15-DAY)		OT	CA-ACCORD-188454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Rituximab			S				Not Reported

	Sulfasalazine	S	Not Reported
	Desoximetasone	C	Not Reported
	Gold	C	Not Reported
	Prednisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988469	EXPEDITED (15-DAY)		OT	CA-ACCORD-188457		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Parenteral			Not Reported
	Adalimumab			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Certolizumab Pegol			S	Subcutaneous	Solution Subcutaneous Single-Use Prefilled Syringe		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sodium Aurothiomalate			S		1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S				Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Azathioprine			C		1 Every 1 Days		Not Reported
	Minocycline			C				Not Reported
	Ciclosporin			C				Not Reported
	Penicillamine			C				Not Reported
	Prednisolone			C		1 Every 12 Hours		Not Reported
	Tocilizumab			C				Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988503	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053848		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Milligram/Sq. Meter, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown	420 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988738	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796215		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural	Gabapentin			S	Oral	200 Milligram Daily;		Ivax
	Methotrexate			S	Subcutaneous			Barr
	Fentanyl			S	Unknown			Cephalon
	Celecoxib			S	Oral			Teva
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram Daily;	Not Reported
	Ergocalciferol	C	Unknown	400 Iu (International Unit) Daily;	Not Reported
	Esomeprazole	C	Unknown	800 Milligram Daily;	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram Daily;	Not Reported
	Loperamide Hydrochloride	C	Unknown		Not Reported
	Nasonex	C	Unknown	4 Dosage Forms Daily;	Not Reported
	Nasonex	C	Unknown	4 Dosage Forms Daily;	Not Reported
	Pantoprazole Magnesium	C	Unknown	40 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Trazodone Hydrochloride	C	Unknown	50 Milligram Daily;	Not Reported
	Tylenol	C	Unknown	100 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988826	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797082			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Rheumatoid Arthritis	Naproxen			S	Oral	1000 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral			Actavis

Arava	S	Oral	10 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
Methotrexate	S	Oral			Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989085	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1796088		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Erythema; Off Label Use; Rash Maculo-Papular	Hydroxychloroquine Sulfate			S	Oral			Teva
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin Sodium			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989322	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052269			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Q4wk		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	5 Milligram, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram Per Cubic Metre, Qwk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	250 Milligram		Not Reported
	Triamcinolone			S	Unknown			Not Reported

	Vaccinia Immune Globulin Intravenous (Human)	S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab	S	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989365	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020255010		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Methylprednisolone Sodium Succinate			S		80 Mg (Day 1 In Bolus)		Pfizer
	Methylprednisolone Sodium Succinate			S		Unk (Descendent Regimen)		Pfizer
	Azithromycin			S		500 Mg, 1x/Day (Every 24h)		Pfizer
	Dolquine			S	Oral	200 Mg, 2x/Day (Every 12h)		Not Reported
	Lopinavir And Ritonavir 200mg/50mg Tablets			S	Oral	2 Tablets, 2x/Day (Every 12h)		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day (Every 24h)		Not Reported
	Metoclopramide			C		Unk		Not Reported
	Metamizole			C		Unk		Not Reported
	Clexane			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989534	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053359		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Specific Antibody Present;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	577 Milligram		Not Reported

Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Anakinra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	577 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Desoximetasone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990152	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1060386		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Mg Le 20/03/2020 Puis 250mg /24h À Partir Du 21/03/2020		Not Reported
	Plaquenil /00072603/			S	Oral	400mg Le 20/03 À 18h30 Et 400mg Le 21/03 À 8h		Mylan
	Norepinephrine			C	Intravenous (not otherwise specified)	32mg/42ml		Mylan
	Cefotaxime Sodium			C		2000 Milligram, Q8h,2g/8h		Mylan
	Bipreterax /01421201/			C	Oral	1 Le Matin		Mylan
	Janumet /06535301/			C		50 Mg/1000 Mg, Comprime Pellicule		Mylan
	Suxamethonium Chloride			C	Intravenous (not otherwise specified)	Unk		Mylan
	Etomidate			C	Intravenous bolus	30 Milligram		Mylan
	Lovenox			C	Subcutaneous	4000 International Unit		Mylan

Propofol	C	Intravenous (not otherwise specified)	Unk		Mylan
Amlodipine	C		10 Milligram,1 Cp Le Soir		Mylan
Sufentanil	C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990522	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054006			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Muscle Disorder; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990608	NON-EXPEDITED			US-PFIZER INC-2020259931		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Impaired Quality Of Life	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990634	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990662	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-21480		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported

	Humira	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990669	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Rash; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053448		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Mobicox			C	Unknown	15 Milligram,1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990858	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw;	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Rheumatoid Arthritis	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990864	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1060462		74 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatic Function Abnormal; Off Label Use	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Plaquinol			S	Oral	200mg De 12/12h		Mylan
	Morphine			C		Unk		Mylan
	Propofol			C	Intravenous (not otherwise specified)	Unk		Mylan
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Mylan
	Clarithromycin			C		Unk		Mylan
	Rocuronium Bromide			C	Intravenous (not otherwise specified)	Unk		Mylan
	Enoxaparin Sodium			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990926	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061550		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Off Label Use	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Edoxaban			S	Oral	60 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990930	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061549		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Apixaban			S	Oral	5 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990931	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061548		86 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Off Label Use	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Dabigatran			S	Oral	110 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990932	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061546		79 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Labelled Drug-Drug Interaction Medication Error; Off Label Use	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Rivaroxaban			S	Oral	15 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990933	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061547		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported

Level Increased; Labelled Drug-Drug Interaction Medication Error; Off Label Use	Rivaroxaban		S	Oral	15 Milligram, Qd	Mylan
	Hydroxychloroquine		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990942	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797102			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swollen Joint Count Increased; Tender Joint Count Increased	Naproxen			S	Oral	1000 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Celebrex			S	Oral	200 Milligram Daily;		Not Reported
	Folic Acid			S	Oral	1 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Ergocalciferol			C	Oral	25 Microgram Daily;		Not Reported
	Lansoprazole			C	Oral	30 Milligram Daily;		Not Reported
	Paroxetine Hydrochloride			C	Oral	20 Milligram Daily;		Not Reported
	Prazosin Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990963	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797098			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Chest Pain; Drug Intolerance; Rheumatoid Arthritis	Naproxen			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Codeine/Phenobarbital			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991006	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053319			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991122	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797105		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing;	Naproxen			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased				otherwise specified)	
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Anakinra		S	Unknown	Not Reported
	Anakinra		S	Subcutaneous	Not Reported
	Etanercept		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Infliximab		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Acetaminophen		C		Not Reported
	Diphenhydramine Hydrochloride		C		Not Reported
	Ferrous Gluconate		C	Unknown	Not Reported
	Folic Acid		C		Not Reported
	Methylprednisolone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991181	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053840			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Arthritis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991262	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991286	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053303		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Qid		Not Reported
Perindopril	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991399	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053174		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991400	EXPEDITED (15-DAY)		OT	NVSC2020ES188226		54 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Nausea	Hydroxychloroquine Sulfate			S	Oral	Unk		Novartis
	Kaletra			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991442	EXPEDITED (15-DAY)		OT	NVSC2020ES188191		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine Sulfate			S	Oral	Unk		Novartis
	Kaletra			S	Oral	4 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991559	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053310			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991678	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017491690		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug	Enbrel			S	Subcutaneous	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer

Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown	Unk		Not Reported
	Adalimumab	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Leflunomide	S	Unknown	Unk, Bid		Not Reported
	Naproxen	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Oral	Unk		Not Reported
	Apo-Naproxen	S	Unknown	Unk		Not Reported
	Apo-Prednisone	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991886	EXPEDITED (15-DAY)		OT	NVSC2020ES188224		39 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Vomiting	Azithromycin			S	Unknown	Unk		Novartis
	Kaletra			S	Oral	4 Df, Qd		Not Reported
	Ceftriaxona			S	Unknown	Unk		Not Reported
	Dolquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17991925	EXPEDITED (15-DAY)		DE	US-PURDUE-USA-2020-0156170		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Hydrocodone Bitartrate/Acetaminophen			S	Oral			Rhodes

	Fenofibrate	S	Unknown	Rhodes
	Lisinopril	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Furosemide	S	Unknown	Not Reported
	Citalopram	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Trazodone	S	Unknown	Not Reported
	Perforomist	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17992077	EXPEDITED (15-DAY)		OT	NVSC2020ES188042		69 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia	Interferon Beta-1b			S	Subcutaneous	30 Ug, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Levofloxacin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17992524	EXPEDITED (15-DAY)		OT	NVSC2020ES188258		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine Sulfate			S	Oral	Unk		Novartis
	Kaletra			S	Oral	4 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17992530	EXPEDITED (15-DAY)		OT	NVSC2020ES188205		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Lopinavir + Ritonavir			S	Oral	Unk		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	800 Mg, Qd		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17992550	EXPEDITED (15-DAY)		OT	NVSC2020ES188227		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Vomiting	Hydroxychloroquine Sulfate			S	Oral	Unk		Novartis
	Azitromicina			S	Unknown	Unk		Not Reported
	Kaletra			S	Oral	4 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17992809	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Folic Acid	S	Unknown	Unk		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17992875	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993064	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-20K-028-3472980-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Arthralgia; Chills; Diarrhoea; Drug Ineffective; Fatigue; Heart Rate Increased; Liver Function Test Increased; Nausea; Ovarian Cyst; Ovulation Pain; Pain; Pyrexia; Quality Of Life Decreased; Rash; Uterine Cyst; Vomiting; Wheelchair User; White Blood Cell Count Increased	Humira			S	Subcutaneous			Not Reported
	Synthroid			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Benadryl			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Cimzia			C				Not Reported
	Cortisone			C				Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993118	EXPEDITED (15-DAY)		OT	CA-ROCHE-2636995		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Memory Impairment; Therapy Partial Responder; Therapy Partial Responder; Therapy Partial Responder	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Leflunomide	C	Unknown			Not Reported
Rosuvastatin	C				Not Reported
Prednisone	C	Unknown	Prn (As Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993196	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	11457282	EXPEDITED (15-DAY)		CA, DS, HO	CA-ROCHE-1626689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Independence In Daily Activities; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	12430958	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016069625		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qwk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	12454121	EXPEDITED (15-DAY)		OT	CA-ROCHE-1771508		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Plaquenil (Hydroxychloroquine Sulfate)		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 190		Not Reported

Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Enbrel	S	Unknown	Days	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methadone	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Ramipril	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic	Solution Opthalmic	Not Reported
	Cosopt	C	Unknown	Eye Drops	Not Reported
	Furosemide	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported

Ergocalciferol	C	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Gravol Ginger	C	Oral			Not Reported
Zingiber Officinale	C				Not Reported
Estrogel	C	Unknown			Not Reported
Estrogel	C	Unknown			Not Reported
Calcium	C	Unknown			Not Reported
Potassium Chloride	C	Unknown			Not Reported
Morphine	C	Unknown	As Needed		Not Reported
Baclofen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	12691420	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016405201		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg		Pfizer
	Sulfasalazine			S		500 Mg		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Minocycline			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Arava			S		100 Mg		Not Reported
	Azathioprine			S		100 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Hydroxyquine			S		400 Mg		Not Reported

	Apo-Azathioprine	S		100 Mg	Not Reported
	Apo-Azathioprine	S		Unk	Not Reported
	Minocycline Hydrochloride	S		Unk	Not Reported
	Hydroxychloroquine	S		400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S		400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	C		Unk	Not Reported
	Leflunomide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	13929661	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2691		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclic		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	14159126	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017165285		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Subcutaneous	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	65 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	65 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	14228796	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3816		75 YR	Female	CAN

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

Arthralgia; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	14634541	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1464		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 730		Not Reported
	Leflunomide			S	Unknown			Not Reported

	Etanercept	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Remicade	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	14920834	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1032511		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Haemophagocytic Lymphohistiocytosis; Herpes Zoster; Listeria Sepsis; Lymphopenia; Progressive Multifocal Leukoencephalopathy	Azathioprine			S		Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	1 G, Unk		Mylan
	Cellcept /01275102/			S	Oral	Unk		Mylan
	Thalidomide Celgene			C	Oral	Unk		Mylan
	Thalidomide Celgene			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	14956006	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2017-04909		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use;	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported

Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Adalimumab	S	Unknown	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)		Not Reported
	Abatacept	S	Intravenous (not otherwise specified)		Not Reported
	Abatacept	S	Intravenous drip		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Unknown	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Unknown	Not Reported
Apo-Triamcinolone Aq	S	Unknown	Spray Metered Dose	Not Reported
Apo-Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Respiratory (inhalation)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous drip		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Intravenous drip		Not Reported
Orencia	S	Respiratory (inhalation)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown, Suspension	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported

Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Humira	S	Subcutaneous	Unknown.	Not Reported
Humira	S	Unknown	Unknown	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Solution	Not Reported
Gammagard	S			Not Reported
Gammagard	S			Not Reported
Kineret	S	Subcutaneous	Per Syringe Single-Use, Preservative-Free Pre-	Not Reported

			Filled Syringes, Solution Subcutaneous	
Kineret	S	Subcutaneous	Per Syringe Single-Use, Preservative-Free Pre-Filled Syringes, Solution Subcutaneous, Unknown	Not Reported
Triamcinolone	S	Unknown	Unknown	Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Triamcinolone	S	Unknown	Unknown	Not Reported
Triamcinolone	S			Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Hexacetonide	S			Not Reported
Triamcinolone Hexacetonide	S			Not Reported
Methotrexate Sodium	S	Unknown	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Unknown	Not Reported
Gamastan	S	Intramuscular	Liquid Intramuscular	Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown, Solution	Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Immunoglobulin [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported

	Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15259000	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1043		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfamethoxazole			S	Unknown			Not Reported

	W/Trimethoprim				
	Penicillin	S	Unknown		Not Reported
	Rocuronium Bromide	S	Unknown		Not Reported
	Rocuronium Bromide	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15268954	EXPEDITED (15-DAY)		HO	CA-ROCHE-2168145			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15327981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175377		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not	Solution Intravenous		Not Reported

Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Solution For Injection In Pre Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Imuran [Azathioprine]	C	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15412513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186027		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Restasis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15580509	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017039792		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Q12h		Pfizer
	Rituximab			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Actemra			S	Endocervical	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day (Daily)	Not Reported
	Leflunomide	S		20 Mg, Daily	Not Reported
	Leflunomide	S	Unknown	10 Mg, 1x/Day	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q12h	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Lyrica	C	Oral	50 Mg Am And 100 Mg Hs	Not Reported
	Naproxen	C		500 Mg, 1x/Day	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15622316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557239-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Impaired Work Ability; Nasopharyngitis; Nasopharyngitis; Rheumatoid Arthritis; Rheumatoid Arthritis; Stress; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15708014	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3644		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	15930315	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2654615-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Irritable Bowel Syndrome; Joint Swelling; Malaise; Nausea; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration-3 Years		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration-11 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form Of Administration-Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

	Tylenol	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Advil	C	Unknown	Not Reported
	Pregabalin	C		Not Reported
	Folic Acid	C		Not Reported
	Acetaminophen W/Codeine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	16142599	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027743		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Milligram 2every 1 Day		Not Reported
	Xeljanz			C	Unknown	1 Gram, 2 Every 1 Day		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C		1 Gram, 2 Every 1 Day		Not Reported

	Arava		C	Unknown			Not Reported
	Humira		C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	16470848	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018036164		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	25 Milligram, Q2wk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Bupropion	C		Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	16481428	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2833864-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	16695051	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2882106-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tylenol Arthritis			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	16714551	EXPEDITED (15-DAY)		OT	PHHY2019DE188505			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	2 Df, Qd (1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Omeprazole			S	Oral	2 Df, Qd (1 Df, 2x/Day (1 - 0 - 1))		Novartis
	Omeprazole			S	Unknown	40 Mg, Qd (20 Mg, Bid)		Novartis
	Pregabalin			S	Unknown	3 Df, Qd		Not Reported
	Apixaban			S	Unknown	2 Df (1 Dosage Form, Bid (1-0-1))		Not Reported
	Apixaban			S	Unknown	5 Mg, Qd (2.5 Milligram, Bid)		Not Reported
	Apixaban			S	Unknown	2.5 Mg, Bid		Not Reported

Apixaban	S	Unknown	2 Df, Qd	Not Reported
Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd (Film Coated Tablet)	Not Reported
Ambrisentan	S	Unknown	1 Df, Qd	Not Reported
Ambrisentan	S	Unknown	Unk	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Quensyl	S	Unknown	2 Df, Qd (1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval)	Not Reported
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Quensyl	S	Unknown	40 Mg, Qd (20 Mg Bid (40 Mg/Day))	Not Reported
Quensyl	S	Unknown	80 Mg, Qd (40 Mg, Bid (80mg/Day))	Not Reported
Quensyl	S	Unknown	20 Mg, Bid (40 Mg/Day)	Not Reported
Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Not Reported
Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Not Reported
Quensyl	S	Unknown	20 Mg, Bid (40 Mg/Day)	Not Reported
Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Not Reported
Quensyl	S	Unknown	20 Mg, Bid (40 Mg/Day)	Not Reported
Quensyl	S	Unknown	20 Mg, Bid (40 Mg/Day)	Not Reported
Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd (Number Of	Not Reported

			Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	
Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported

Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
Eliquis	S	Unknown	2 Df, Qd	Not Reported
Eliquis	S	Unknown	2.5 Mg Bid	Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw (Solution For Injection In Pre-Filled Syringe)	Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Lyrica	S	Unknown	300 Mg, Qd (100 Milligram, Tid)	Not Reported
Lyrica	S	Unknown	3 Df, Qd (1 Df, Tid (1 Df, 3x/Day (1 - 1- 1)))	Not Reported
Lyrica	S	Unknown	100 Mg, Tid	Not Reported
Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))	Not Reported

Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))		Not Reported
Lyrica	S	Unknown	100 Mg, Tid		Not Reported
Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))		Not Reported
Lyrica	S	Unknown	100 Mg, Tid		Not Reported
Lyrica	S	Unknown	100 Mg, Tid		Not Reported
Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))		Not Reported
Tocilizumab	S	Subcutaneous	162 Mg, Qw		Not Reported
Tocilizumab	S	Subcutaneous	162 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	16923698	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000576			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran /00001502/			S	Unknown	Unk		Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid		Not Reported
Ezetrol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17284429	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000044			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Arava			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg, Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Ezetrol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17353593	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530486		51 YR	Male	CAN

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

Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17444031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554290		36 YR	Female	CAN

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

Ineffective; Off Label Use; Osteoarthritis; Synovitis	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Arava	C		Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17529190	EXPEDITED (15-DAY)		OT	NVSC2020AU065740			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Eye Movement Disorder; Mobility Decreased; Scleroderma; Therapeutic Product Effect Incomplete	Tacrolimus			S	Unknown	Unk		Novartis
	Ruxolitinib			S	Unknown	10 Mg, Bid		Not Reported
	Prednisone			S	Unknown	10 Mg		Not Reported
	Prednisone			S	Unknown	Up To 50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	0.25 Mg/Kg		Not Reported
	Prednisolone			S	Unknown	1 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17558470	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020114627		50 YR	Female	CAN

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

Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Enbrel	S	Unknown	Unk	Unknown
	Methotrexate Sodium	S	Unknown	25 Milligram	Pfizer
	Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
	Xeljanz	S	Oral	5 Milligram, Qd	Pfizer
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17596954	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068451			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	20 Mg		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Celecoxib			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

	Cimzia		S	Subcutaneous	Unk	Not Reported
	Folic Acid		C	Oral	5 Mg	Not Reported
	Prednisone		C	Oral	Unk	Not Reported
	Xeljanz		C		Unk	Not Reported
	Desoximetasone		C		Unk	Not Reported
	Leflunomide		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17658388	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Subcutaneous	17 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S		20 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Ev 4 Weeks		Not Reported
	Sulfasalazine			S		1 Gram, 2x/Day (Bid)		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17686390	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032357		61 YR	Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Actemra	S	Unknown	8 Milligram/Kilogram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17739897	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590110		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous	8.0 Months		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Esomeprazole Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Nicotinamide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported

	Sarilumab	S	Subcutaneous	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Thiamine Hydrochloride	S	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Kevzara	S	Subcutaneous	Not Reported
	Kevzara	S	Unknown	Not Reported
	Dexpanthenol	C		Not Reported
	Ergocalciferol	C		Not Reported
	Esomeprazole	C		Not Reported
	Esomeprazole Magnesium Trihydrate	C		Not Reported
	Nexium [Esomeprazole Magnesium]	C		Not Reported
	Riboflavin	C		Not Reported
	Vitamin A [Retinol]	C		Not Reported
	Vitamin C [Ascorbic Acid]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17749115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17794364	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247343		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Mg Dia		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	In Total		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Compri...			S	Oral	2u Cada 12h		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17795880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597666		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate	S	Unknown		Not Reported
	Risedronate	S	Unknown		Not Reported
	Risedronate Sodium	S	Oral		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17810580	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2601602		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Oxycodone	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	C	Unknown	Not Reported
Kineret	C		Not Reported
Lyrica	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17814676	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597811		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain;	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported

Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Diclofenac	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17825445	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599544		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Months		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 610.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Oral	Therapy Duration: 2.0 Months	Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 2.0 Months	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17845790	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606657			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Gold	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17855326	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1053156		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Intentional Product Use Issue; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Bid		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Mylan
	Roactemra			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Mylan
	Enoxaparin			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17876548	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3436071-00		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Electrocardiogram Qt Prolonged; Hepatitis Toxic; Hyperbilirubinaemia; Hypertransaminasaemia; Ischaemia; Obstructive Airways Disorder; Off Label Use; Peripheral Arterial Occlusive Disease; Secretion Discharge; Thrombosis	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17889185	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA162322		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported

	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17890436	EXPEDITED (15-DAY)		OT	NVSC2020CA163937			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Drug Ineffective; Headache; Musculoskeletal Stiffness; Pain In Extremity; Rash	Methotrexate			S	Subcutaneous	25 Mg		Novartis
	Methotrexate			S	Oral	Unk Unk, Qd		Novartis
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown	150 Mg, Qd		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Tylenol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17928081	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012400			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Cimzia			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Arava			C	Unknown	Unk		Not Reported

Depo-Medrol	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17936660	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP012409			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Plaquenil /00072603/			C	Oral	200 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17940598	EXPEDITED (15-DAY)		HO, OT	TN-SA-2020SA154985			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Eosinophilia; Leukocytosis; Neutrophilia; Off Label	Plaquenil			S		600 Mg, Qd		Sanofi
	Plaquenil			S				Sanofi
	Enoxaparin Sodium			S		Unk		Sanofi
	Oxygen			C		Unk		Not Reported

Use; Pruritus; Pustule;
Skin Plaque

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17954394	EXPEDITED (15-DAY)		HO	CA-ROCHE-2623759		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2555.0 Days		Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Nortriptyline Hydrochloride			S	Oral			Not Reported
	Orencia			S	Vaginal			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	330.0 Days		Not Reported
	Orencia			S	Subcutaneous	330.0 Days		Not Reported
	Oxycontin			S	Unknown			Not Reported

Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Sulfasalazine	S	Oral	1825.0 Days	Not Reported
	Sulfasalazine	S	Oral	1825.0 Days	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Oral		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C			Not Reported
	Aclasta	C			Not Reported
	Ascorbic Acid	C			Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride	C			Not Reported
	Biotin	C			Not Reported
	Calcium	C			Not Reported
	Cyanocobalamin	C			Not Reported
	D-Alpha Tocopherol	C			Not Reported
	Diphenoxylate Hydrochloride	C			Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C			Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported
	Fergon	C			Not Reported
	Ferrous Fumarate	C			Not Reported
	Ferrous Gluconate	C			Not Reported
	Fish Oil;Tocopherols Mixed	C			Not Reported
	Folic Acid	C			Not Reported
	Genteal Lubricant	C			Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C			Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Esomeprazole	C			Not Reported
	Nicotinamide	C			Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Perphenazine	C	Oral		Not Reported

Omega-3 Fatty Acids	C		Not Reported
Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
Oxycodone Terephthalate	C		Not Reported
Pantoprazole	C		Not Reported
Pantoprazole Magnesium	C		Not Reported
Prednisone	C		Not Reported
Pyridoxine	C		Not Reported
Pyridoxine Hydrochloride	C		Not Reported
Retinol Palmitate	C		Not Reported
Riboflavin	C		Not Reported
Risedronate Sodium	C		Not Reported
Sodium Ascorbate	C		Not Reported
Thiamine Hydrochloride	C		Not Reported
Thiamine Mononitrate	C		Not Reported
Trazodone Hydrochloride	C		Not Reported
Tylenol	C		Not Reported
Vitamin A [Retinol]	C		Not Reported
Vitamin B1 [Thiamine]	C		Not Reported
Vitamin C [Ascorbic Acid]	C		Not Reported
Vitamin D3	C		Not Reported
Acetaminophen	C	Oral	Not Reported
Actonel	C	Unknown	Not Reported
Oxycodone Hydrochloride	C	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Tecta	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17982892	EXPEDITED (15-DAY)		HO, LT, OT	BE-MYLANLABS-2020M1061781		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Abuse; Haemolysis; Intentional Overdose; Intentional Product Misuse; Off Label Use; Renal Ischaemia; Toxicity To Various Agents	Hydroxychloroquine			S		Unk		Mylan
	Azithromycin			C		Unk		Mylan

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17991277	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052993		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Orencia			S	Unknown	760 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	680 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	360 Milligram, Qmo		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	70 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17991693	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3469071-00		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Infection; Insomnia; Joint Swelling; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17991731	EXPEDITED (15-DAY)		OT	CA-ROCHE-2636836		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Winpred	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17991839	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-032097		68 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Interstitial Lung Disease; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Prednisone			S	Unknown	5 Milligram/Kilogram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Once A Day		Not Reported
	Methylprednisolone			S	Unknown	1 Milligram/Kilogram		Not Reported
	Lopinavir;Ritonavir			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17992122	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-032307		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ejection Fraction Decreased; Heart Rate Decreased; Off Label Use; Pulseless Electrical Activity	Furosemide			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Milligram, Four Times/Day		Aurobindo
	Methylprednisolone			S	Intravenous (not otherwise specified)	100 Milligram, Daily		Aurobindo
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	400 Milligram, Two Times A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Milligram		Not Reported
	Norepinephrine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17992798	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202005006833			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Placental Insufficiency; Premature Baby	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	1 Dosage Form, Bid		Concordia
	Clexane			S	Transplacental	Unk, Qd (0.4)		Not Reported
	Clexane			S	Transplacental	Unk Unk, Bid (0.4)		Not Reported
	Clexane			S	Transplacental	Unk, Bid (0.4)		Not Reported
	Prednisone			S	Transplacental	8 Dosage Form, Qd (4 Tablets In The Morning, 3 Tablets At Noon, 1 Tablet In The Evening)		Not Reported
	Methylprednisolone			S	Transplacental	8 Dosage Form, Qd		Not Reported
	Methylprednisolone			S	Transplacental	Sodium Chloride Solution 0.9% - 100.0 Iv Within 30 Min		Not Reported
	Methylprednisolone			S	Transplacental	Sodium Chloride Solution		Not Reported

			0.9% - 100.0 Iv Dri Pn Monday And Thursday	
Nifedipine	S	Transplacental	30 Mg, Bid	Not Reported
Nifedipine	S	Transplacental	30 Mg, Qd	Not Reported
Nifedipine	S	Transplacental	30 Mg, Qd	Not Reported
Nifedipine	S	Transplacental	90 Mg, Qd, (60 Mg In The Morning, 30mg In The Evening)	Not Reported
Methyldopa	S	Transplacental	0.5 Dosage Form, Qd	Not Reported
Methyldopa	S	Transplacental	0.5 Dosage Form, Tid	Not Reported
Methyldopa	S	Transplacental	1.5 Dosage Form, Qd	Not Reported
Methyldopa	S	Transplacental	1.5 Dosage Form, Qd	Not Reported
Omeprazole	S	Transplacental	1 Dosage Form, Bid	Not Reported
Levothyroxine Sodium	S	Transplacental	Unk	Not Reported
Progesterone	S	Transplacental	400 Mg, Qd, From 14 Weeks	Not Reported
Fosfomycin	S	Transplacental	3 G, Qd (Hs)	Not Reported
Fosfomycin	S	Transplacental	3 G, Weekly (On Friday)	Not Reported
Dipyridamole	S	Transplacental	75 Mg, Bid	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Transplacental	1 Dosage Form, Tid	Not Reported
Folic Acid	S	Transplacental	1 Dosage Form, Tid	Not Reported
Cefepime Hydrochloride	S	Transplacental	Unk	Not Reported
Magnesium Sulfate	S	Transplacental	Unk	Not Reported
Ceftaroline Fosamil	S	Transplacental	600 Mg, Sodium Chloride Solution 0.9% -100.0, Every 12 Hours For 10 Days Iv Slowly Within An Hour	Not Reported
Suprastin	S	Transplacental	1 Dosage Form, Qd (Hs)	Not Reported
Suprastin	S	Transplacental	1 Dosage Form, Bid	Not Reported
Azathioprine	S	Transplacental	50 Mg, Qd, In The Morning	Not Reported

	Azathioprine		S	Transplacental	50 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17992837	EXPEDITED (15-DAY)		LT, OT	CA-ACCORD-189070			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Methotrexate			S	Oral	1 Every 1 Weeks, Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Celebrex			S	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Folic Acid			C	Unknown	4 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17992844	EXPEDITED (15-DAY)		OT	CA-ACCORD-189072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Flank Pain; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased; White Blood Cell Disorder	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Desoximetasone			C	Intramuscular	Not Specified,As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17992846	EXPEDITED (15-DAY)		OT	CA-ACCORD-189074			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17992848	EXPEDITED (15-DAY)		OT	CA-ACCORD-189075			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17993263	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2087124			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Product Substitution Issue; Pruritus; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17993264	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053711		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Therapeutic Response Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17993838	NON-EXPEDITED			US-APPCO PHARMA LLC-2087125			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17993890	EXPEDITED (15-DAY)		OT	CA-ACCORD-189021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S				Accord
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituximab			S				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17993902	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1797785			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Swollen Tongue	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17993998	EXPEDITED (15-DAY)		OT	CA-ROCHE-2637865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Aluminium Acetate	C	Unknown	Not Reported
	Atacand	C	Unknown	Not Reported
	Benzethonium Chloride	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	Neurontin	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994187	EXPEDITED (15-DAY)		OT	NVSC2020ES188179		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis	Hydroxychloroquine Sulfate			S	Oral	Unk		Novartis
	Azithromycin			S	Oral	Unk		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994194	EXPEDITED (15-DAY)		HO	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-052575			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia;	Hydroxychloroquine Sulfate			S	Oral	200 Milligram (20 Tablets)		Zydus Pharm

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haemoglobin Decreased; Hypokalaemia; Intentional Overdose; Nausea; Platelet Count Decreased; Somnolence; Suicide Attempt; Ventricular Tachycardia; Vomiting	Tablet					
	Methotrexate Tab 2.5mg		S	Oral	2.5 Milligram (30 Tablets)	Zydus Pharm
	Prednisone		S	Unknown	10 Milligram (30 Tablet)	Not Reported
	Diazepam		S	Intravenous bolus	1 Milligram/Kilogram Over 30 Minutes	Not Reported
	Diazepam		S	Intravenous bolus	6.5 Milligram Every 2 Hours	Not Reported
	Diazepam		S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Diazepam		S	Intravenous bolus	80 Milligram	Not Reported
	Diazepam		S	Intravenous bolus	39 Milligram Every 2 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994215	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053290			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	640 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	640 Milligram, Q4wk		Not Reported
	Arava			S	Oral	Unk, Qwk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Milligram, Q2wk		Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not	300 Milligram, Qwk		Not Reported

			otherwise specified)		
	Lyrica	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Piroxicam	C	Unknown		Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994384	EXPEDITED (15-DAY)		OT	NVSC2020ES188196		29 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Q24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994425	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050670			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Paracetamole			S	Intravenous (not otherwise specified)	1 Gram, Tid (Every 8 Hours)		Not Reported
	Dolquine			S	Oral	400 Milligram, Qd		Not Reported
	Dolquine			S				Not Reported

	Ceftriaxone		S	Intravenous (not otherwise specified)	2 Gram, Qd	Not Reported
	Ceftriaxone		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994486	EXPEDITED (15-DAY)		OT	NVSC2020ES186724		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azitromicina			S	Oral	Unk		Novartis
	Cceftriazona [Ceftriaxone Sodium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994525	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061552		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Labelled Drug-Drug Interaction Medication Error; Off Label Use	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Rivaroxaban			S	Oral	20 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994526	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061553		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Apixaban			S	Oral	5 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994535	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1061551		89 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Apixaban			S	Oral	2.5 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994561	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES190414		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Delusion; Hallucinations, Mixed; Hyperglycaemia; Hypervigilance; Insomnia; Irritability; Logorrhoea; Mania; Product Use In Unapproved Indication; Psychomotor Hyperactivity; Renal Failure; Restlessness	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Lopinavir,Ritonavir			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	High Dose		Not Reported
	Methylprednisolone			S	Unknown	32 G, Qd (At Discharge)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994571	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017216863		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, 1x/Day		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Pfizer

	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994577	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3473114-00		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Kaletra 200/50			S	Oral	400/100 Mg Cada 12 Horas		Not Reported
	Dolquine			S	Oral	200 Mg Cada 12 Horas, Con 400 Mg/12h De Dosis De Carga El Primer Día		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994760	EXPEDITED (15-DAY)		OT	CA-ACCORD-189002		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Accord
	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Infliximab			S	Intravenous (not			Not Reported

			otherwise specified)			
	Risedronic Acid	S	Unknown	1 Every 1 Weeks		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994785	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061653		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Prednisone			S	Unknown	30 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Rituximab			S				Mylan
	Tocilizumab			S	Unknown	400 Milligram, One Dose		Mylan
	Bactrim			C	Unknown			Mylan
	Famotidine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994787	EXPEDITED (15-DAY)		OT	CA-ACCORD-188435		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis;	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S				Not Reported
	Paracetamol			C				Not Reported

Therapeutic Product Effect Incomplete	Anakinra	C			Not Reported
	Ativan	C			Not Reported
	Benadryl	C			Not Reported
	Codeine	C			Not Reported
	Darifenacin/Darifenacin Hydrobromide	C			Not Reported
	Desoximetasone	C			Not Reported
	Dilaudid	C			Not Reported
	Hydromorphone/Hydromorphone Hydrochloride	C			Not Reported
	Kadian	C		Capsule,Sustained Release	Not Reported
	Kenalog	C		Suspension Intra- Articular	Not Reported
	Lasix	C			Not Reported
	Loperamide	C			Not Reported
	Norflex	C			Not Reported
	Omnaris	C		Spray, Metered Dose	Not Reported
	Orphenadrine	C			Not Reported
	Oxyneo	C		Tablet (Extended-Release)	Not Reported
	Pantoloc	C			Not Reported
	Pantoprazole	C			Not Reported
	Restasis	C		Emulsion	Not Reported
	Rituximab	C	Intravenous drip		Not Reported
	Synthroid	C			Not Reported
	Trimethoprim	C			Not Reported
	Urispas	C			Not Reported
	Vagifem	C		Vaginal Suppository	Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994789	EXPEDITED (15-DAY)		OT	CA-ACCORD-188995		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand	Methotrexate			S	Unknown	1 Every 1 Days		Accord
	Actemra			S	Unknown			Not Reported

Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994794	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796910		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Xeljanz	S	Oral			Not Reported
Folic Acid	C	Subcutaneous			Not Reported
Folic Acid	C	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994806	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1797050		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994812	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1797230		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral	2.6 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone			S	Other			Not Reported
	Triamcinolone Hexacetonide			C	Intra-articular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994902	EXPEDITED (15-DAY)		OT	CA-ACCORD-188729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During	Methotrexate			S	Oral			Accord
	Tofacitinib			S				Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound				otherwise specified)		
	Prednisone		S			Not Reported
	Phthalylsulfathiazole		S			Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S		1 Every 1 Days	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Fosamax		S	Oral		Not Reported
	Folic Acid		S			Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Desoximetasone		S	Oral		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Cetirizine		S			Not Reported
	Arava		S	Oral		Not Reported
	Tocilizumab		S			Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate		S	Unknown		Accord
	Hydroxychloroquine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994905	EXPEDITED (15-DAY)		OT	CA-ACCORD-189369			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Methotrexate			S	Oral			Accord
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Solution Subcutaneous		Not Reported
	Sulfasalazine	S			Not Reported
	Folic Acid	C			Not Reported
	Pantoprazole	C			Not Reported
	Tenofovir	C			Not Reported
	Xeljanz	C			Not Reported
	Zopiclone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994942	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020260577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Endocervical	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995336	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Naproxen		S	Unknown	Unk	Not Reported
	Naproxen Sodium		S	Oral	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Tocilizumab		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	5 Milligram, 2 Every 1 Days	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995470	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797539			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Naproxen			S	Oral	1000 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995504	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797346		53 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995563	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1797298		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height	Naproxen			S	Unknown			Teva

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral	2.6 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone	S	Other			Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995568	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1797205		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	.4286 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995597	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK202006845		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Haloperidol Injection (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Ritonavir/Lopinavir			S	Unknown	400 Mg/100 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995819	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200703536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072603/	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995846	EXPEDITED (15-DAY)		HO	NVSC2020ES188831		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Persecutory Type; Mixed Liver Injury	Tacrolimus			S	Oral	8 Mg, Qd		Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Metoclopramida			S	Intravenous (not otherwise specified)	10 Mg, Q12h		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Mg, Qd		Not Reported
	Prednisona			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995853	EXPEDITED (15-DAY)		HO	NVSC2020ES180766		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination	Interferon Beta-1b			S	Unknown	250 Mg, Q48h		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Enoxaparina			C	Unknown	Unk		Not Reported
	Kaletra			C	Unknown	Unk		Not Reported
	Genvoya			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996015	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053693		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Intentional Product Use Issue; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous drip	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous drip	Unk, Qmo		Bristol Myers Squibb
	Orencia			S		250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 2 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1 Every 2 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Etanercept	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Etanercept	S	Subcutaneous	25 Milligram, 2 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q6wk	Not Reported
	Infliximab	S	Unknown	Unk, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Bristol Myers Squibb
	Folic Acid	C	Unknown	Unk	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996016	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797100		3 YR	Female	CAN

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

Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen	S	Unknown		Teva
	Methotrexate	S	Unknown		Barr
	Prednisone	S	Oral		Actavis
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Unknown	50 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram Daily;	Not Reported
	Infliximab	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	250 Milligram Daily;	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996017	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Naproxen			S	Unknown			Teva
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S				Barr
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
Methotrexate	S	Oral			Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Acetylsalicylic Acid	C	Unknown			Not Reported
Calcium	C	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Lantus	C	Unknown			Not Reported
Lozide	C	Unknown			Not Reported
Metformin	C	Oral			Not Reported
Prednisone	C	Unknown			Not Reported
Ramipril	C	Unknown			Not Reported
Vitamin D3	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996051	EXPEDITED (15-DAY)		OT	HU-TEVA-2020-HU-1797097		18 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination	Hydroxychloroquine			S	Oral	The First Day 400 Mg Twice Daily, Then 200 Mg Twice Daily,		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996100	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1797383		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Azitromicina (7019a)			S	Unknown	500 Mg		Not Reported

	Metilprednisolona (888a)	S	Unknown	Day 1: Bolus Of 80mg, From 08/04 To 16/04 In Descending Guide, Unit Dose: 40 Mg	Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido	S	Oral	2 Dosage Forms	Not Reported
	Ceftriaxona 2.000 Mg Inyectable Iv	S	Intravenous (not otherwise specified)	2 Gm, Form Of Admin. Text : Injection Iv	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos	S	Oral	200 Mg	Not Reported
	Metamizol 2.000 Mg Inyectable 5 Ml	C			Not Reported
	Clexane 4.000 Ui (40 Mg)/ 0,4 Ml Solucion Inyectable En Jeringa Preca	C			Not Reported
	Omeprazol 20 Mg Capsula	C			Not Reported
	Metoclopramida 10 Mg Inyectable 2 Ml	C			Not Reported
	Paracetamol 1.000 Mg Inyectable Perfusion 100 Ml	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996208	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053330		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Orencia			S	Subcutaneous	12.5 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Leflunomide	S	Oral	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram		Not Reported
Methotrexate	S	Oral	20 Milligram		Not Reported
Neoral	S	Subcutaneous	Unk Milligram/Kilogram		Not Reported
Remicade	S	Unknown	3.0 Milligram/Kilogram		Not Reported
Rituximab	S	Endocervical	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996267	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	20 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Q12h		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996290	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020259550		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Unknown
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996390	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1797330		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported

	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996435	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061884		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996450	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061886		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996451	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1061888		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996455	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061883		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996458	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061889		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Belatacept			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996769	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061880		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996783	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1061875		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Off Label Use	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996790	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061882		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996792	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061877		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996794	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061881		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolic Acid			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996796	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1061879		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996798	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1061878		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996800	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1061876		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Off Label Use	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Belatacept			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996841	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000565			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash Pustular	Furosemide			S	Oral	120 Mg, Qd		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Atorvastatin Calcium			S	Oral	20 Mg, Qd		Not Reported

Lantus	S	Subcutaneous	Unk	Not Reported
Allopurinol	S	Oral	300 Mg, Qd	Not Reported
Colecalciferol	S	Oral	Unk	Not Reported
Atenolol	S	Oral	50 Mg, Qd	Not Reported
Azithromycin	S	Oral	Unk	Not Reported
Flecainide Acetate	S	Oral	100 Mg, Qd (Breakable Tablet)	Not Reported
Cortancyl	S	Oral	7.5 Mg, Qd (Compressed)	Not Reported
Novorapid	S	Subcutaneous	Unk	Not Reported
Advagraf	S	Oral	1 Df, Qd	Not Reported
Aranesp	S	Subcutaneous	40 Mg, Qw	Not Reported
Nicardipine	S	Oral	100 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996990	EXPEDITED (15-DAY)		OT	NVSC2020FR185671		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Hydrochlorothiazide			S	Unknown	Unk		Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Tid		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Enoxaparin Sodium			S	Intramuscular	4000 Iu, Qd		Not Reported
	Spironolactone			C	Unknown			Not Reported
	Esidrex			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported

	Levothyrox	C	Unknown	Not Reported
	Tanganil	C	Unknown	Not Reported
	Euthyrox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997026	EXPEDITED (15-DAY)		HO	NVSC2020ES188313		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd (400 Mg Dia)		Novartis
	Amoxicillin Sodium,Potassium Clavulanate			S	Unknown	Unk		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997057	EXPEDITED (15-DAY)		OT	NVSC2020ES186923		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azitromicina			S	Unknown	Unk		Novartis
	Kaletra			S	Oral	Unk		Not Reported
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Ceftriaxona			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997085	EXPEDITED (15-DAY)		HO	BR-MYLANLABS-2020M1061770		29 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997097	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1061805		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Retinal Detachment	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Azithromycin			S		500 Milligram, Qd		Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd		Mylan
	Dolquine			S	Oral	200 Milligram, Bid		Mylan
	Metilprednisolona /00049601/			S		Dia 1: Bolo De 80mg, Del 08/04 Al 16/04 En Pauta Descendente		Mylan
	Metamizol /06276701/			C		2mg/5ml		Mylan
	Clexane			C		(40 Mg/ 0.4 Ml)		Mylan
	Omeprazol /00661201/			C		Unk		Mylan
	Metoclopramida /00041901/			C		10mg/ 2 Ml		Mylan
	Paracetamol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997555	EXPEDITED (15-DAY)		OT	NVSC2020ES186790		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Azithromycin			S	Oral	500 Mg, Q12h		Novartis
	Azithromycin			S				Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Q12h		Not Reported
	Hydroxychloroquine			S				Not Reported
	Ceftriaxona			S	Unknown	2 G, Qd		Not Reported
	Ceftriaxona			S				Not Reported
	Heparina			C	Unknown			Not Reported
	Lopinavir/Ritonavir			C	Oral	1 Df, Q12h		Not Reported
	Lopinavir/Ritonavir			C				Not Reported

	Sintrom			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054356			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997616	EXPEDITED (15-DAY)		OT	NVSC2020ES186799		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azitromicina			S	Oral	Unk		Novartis
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Q12h		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997623	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054346		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Abatacept			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Loperamide			C	Oral	2 Milligram		Not Reported
	Align			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997688	EXPEDITED (15-DAY)		OT	NVSC2020ES186735		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertriglyceridaemia; Rhabdomyolysis	Azitromicina			S	Oral	Unk		Novartis
	Kaletra			S	Oral	2 Df, Q12h		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998824	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	11385922	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ROCHE-1619365		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Herpes Zoster; Intentional Product Use	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported

	Minocycline Hydrochloride	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S		Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Urelumab	C		Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	11567356	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1638076		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal;	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 153 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Prednisone	S	Oral	Therapy Duration: 10 Years	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 63 Days, Therapy Duration: 3 Months	Not Reported
	Orencia	S	Respiratory (inhalation)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Qmo	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 3 Months Therapy Duration: 62 Days	Not Reported
	Kineret	S	Subcutaneous	Therapy Duration: 700 Days, Therapy Duration: 3 Years	Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 8.0 Month(S)	Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 4 Months	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Infliximab	S	Intravenous (not		Not Reported

		otherwise specified)		
Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 5 Months	Not Reported
Infliximab	S	Unknown	Therapy Duration: 62 Days	Not Reported
Sulfasalazine	S	Oral	500 Mg Tablet	Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Iviglob-Ex	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Iviglob-Ex	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Iviglob-Ex	S	Unknown		Not Reported
Iviglob-Ex	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Abatacept	S	Intravenous (not otherwise specified)		Not Reported
Abatacept	S	Intravenous drip	Therapy Duration: 3 Months	Not Reported
Anakinra	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
Anakinra	S	Unknown		Not Reported
Anakinra	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular	Not Reported
Etanercept	S	Subcutaneous	Therapy Duration: 8.0 Months	Not Reported
Etanercept	S	Subcutaneous	Cyclic Therapy Duration: 4 Months, (93 Day)	Not Reported
Etanercept	S	Subcutaneous	Therapy Duration: 8.0 Month(S)	Not Reported

Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S			Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Gamastan	S	Intramuscular		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Folic Acid	C			Not Reported
Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	12085936	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015167344		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S		50 Mg		Unknown
	Methotrexate Sodium			S		Unk		Pfizer

Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Sulfasalazine	S		Unk	Pfizer
	Apo-Leflunomide	S		Unk Usual Dose Greater Than 3months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk, Usual Dose Greater Than 3month	Not Reported
	Humira	S	Subcutaneous	Unk, Usual Dose Greater Than 3month	Not Reported
	Cimzia	S	Subcutaneous	Usual Dose Greater Than 3 Month	Not Reported
	Actemra	S		Unk, Usual Dose Greater Than 3month	Not Reported
	Arava	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Simponi	S		Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Cymbalta	C		Unk	Not Reported
	Hydromorphone	C		Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	12674918	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0935		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C	Unknown	Not Reported

	Prednisone		C	Unknown	Not Reported
	Lyrica		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	12689305	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1444		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Apo Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	13059019	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-APOTEX-2016AP015792		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	500 Milligram		Apotex
	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S			Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Plaquenil /00072602/	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Xeljanz	S	Oral	Unk, Bid	Not Reported
	Xeljanz	S	Unknown	5 Mg, Q.O.Wk.	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported

Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Marijuana	S	Unknown	Unk		Not Reported
Cannabis Sativa	S	Unknown	Unk		Not Reported
Kineret	C	Unknown	Unk		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Plaquenil /00072602/	C	Oral	Unk		Not Reported
Prednisone	C	Unknown	Unk Unk, Qd		Not Reported
Rituximab W/Urelumab	C	Unknown	Unk		Not Reported
Urelumab	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	13111752	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1876541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 12 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

Related Reaction; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months	Not Reported
	Orencia	S	Unknown	Therapy Duration: 9 Months	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 365 Nos Powder For Intravesical Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral	Film-Coated Tablet	Not Reported
	Leflunomide	S	Oral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	7300 Days	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported

	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	13823542	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2252		65 YR	Female	CAN

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

	Simponi	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	13947306	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875144		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Off Label Use; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Cannabis Sativa	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	13984193	EXPEDITED (15-DAY)		OT	CA-ROCHE-1993146			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 4 Years		Not Reported

	Meloxicam	C			Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	14236211	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	15066519	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0720		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism;	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Gold	S	Subcutaneous	Not Reported
	Ilaris	C	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	15449468	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0912		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Overdose; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Codeine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	15457719	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191504		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	15635162	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous	50 Mg, Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, Qwk		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram/Sq. Meter, 1 Every 1 Week		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S		280 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported

	Apo-Prednisone	S	Oral	3 Milligram, Bid		Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid		Not Reported
	Triamcinolone	C	Unknown			Not Reported
	Triamcinolone Hexacetonide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	15953507	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012131		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S		Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	16138972	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0924		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	16214358	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1183			Female	CAN

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

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	16473518	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1968		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	16641493	EXPEDITED (15-DAY)		HO	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-214444		34 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pustular Psoriasis	Hydroxychloroquine			S	Unknown	200 Milligram, Daily		Sun
	Prednisolone			C	Unknown	20 Milligram, Daily		Not Reported
	Prednisolone			C	Unknown	13 Milligram, Daily		Not Reported
	Prednisolone			C	Unknown	Increased To 58 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	16705069	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888307-00			Female	USA

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

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	16842040	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27131		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Plaquenil	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen	C	Unknown	Unknown	Not Reported
Cortisone	C	Unknown	Unknown	Not Reported
Dexamethasone	C	Unknown	Unknown	Not Reported
Gabapentin	C	Unknown	Unknown	Not Reported
Reactine	C	Unknown	Unknown	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unknown	Not Reported
Desoximetasone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17104914	EXPEDITED (15-DAY)		CA, DS, OT	NVSC2019FR050452			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy;	Trileptal			S	Transplacental	Unk		Novartis

Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Paracetamol	S	Transplacental	Unk	Not Reported
	Keppra	S	Transplacental	Unk	Not Reported
	Keppra	S	Transplacental	Maternal Dose 3000 Mg, Qd	Not Reported
	Plaquenil	S	Transplacental	Unk	Not Reported
	Actonel	C	Transplacental	Unk	Not Reported
	Speciafoldine	C	Transplacental	Unk	Not Reported
	Kaleorid	C	Transplacental	Unk	Not Reported
	Orocal D3	C	Transplacental	Unk	Not Reported
	Diffu-K	C	Transplacental	Unk	Not Reported
	Cortancyl	C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17233191	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508660		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nephrolithiasis; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral	Therapy Duration: 4.0		Not Reported

			Months	
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 6.0 Months	Not Reported
Sulfasalazine	S	Oral		Not Reported
Tylenol	S	Unknown		Not Reported
Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Celebrex	C	Oral		Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Tylenol W/Codeine No. 3	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17235412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508236		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis;	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17267089	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517549		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)			Not Reported

	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Not Reported
	Amitriptyline	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17310017	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527625		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17401991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541350		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Durationl- 6.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Durationl- 4.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Durationl-730.0		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17412439	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17695454	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2752444-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Imuran			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Day 1 And Day 15 Every 6 Months		Not Reported
	Actemra			S	Unknown			Not Reported
	Lederle Leucovorin			S	Unknown			Not Reported
	Prevnar 13			S	Intramuscular			Not Reported
	Depo-Medrol With Lidocaine			S	Unknown	40-10 Mg/Ml		Not Reported
	Apo-Prednisone			S	Unknown	Taper Monthly		Not Reported
	Ketoprofen			S	Topical			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Leucovorin Calcium			S	Unknown			Not Reported
	Azathioprine Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17721783	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588811		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17778082	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505939		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Plaquenil /00072602/			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Apo-Leflunomide	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Plaquenil /00072602/	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Acetaminophen W/Caffeine	C		Not Reported
Folic Acid	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	Not Reported

Phosphate				
Arava	C	Oral		Not Reported
Tylenol With Codeine	C	Unknown		Not Reported
Cimzia	C	Subcutaneous		Not Reported
Risedronate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17806683	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance; Drug Tolerance Decreased; Hepatic Enzyme Increased; Nausea; Off Label Use; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Apo-Leflunomide	S	Unknown			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Arava	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Plaquenil /00072602/	S	Unknown			Not Reported
Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
Methotrexate	S	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C	Oral			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Wellbutrin	C	Unknown	Extended-Release		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17808093	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598666			Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17812669	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517507		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17813033	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Bupropion			C				Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C		Tablet (Extended-Release)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17817367	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1051084		77 YR	Male	ITA

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

Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin	S	Oral	1 Dosage Form, Qd		Not Reported
	Plaquenil /00072603/	S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17820507	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600110		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Intentional Product Use Issue; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Tofacitinib Citrate	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Rabeprazole Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17835105	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528683		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17847685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606636		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma;	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Morphine	C		Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Zingiber Officinale	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17906131	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2619986		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17930275	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012397			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17933235	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012395			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17936345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17942631	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pancytopenia; Rash	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Asaphen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17943427	EXPEDITED (15-DAY)		DE	NVSC2020ES177227		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported
	Kaletra			S	Oral	2 Df, Q12h (2u Cada 12h)		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17950522	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2020M1057886		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Covid-19; Covid-19 Pneumonia; Intentional Product Misuse; Off Label Use; Pyrexia	Glatiramer			S	Unknown	Unk		Not Reported
	Fingolimod			S		0.5 Mg, Qd		Not Reported
	Teriflunomide			S	Unknown	Unk		Mylan
	Mitoxantrone			S	Unknown	Unk		Mylan
	Ifn Beta			S	Unknown	Unk		Mylan
	Hydroxychloroquine Sulfate			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17959391	EXPEDITED (15-DAY)		OT	IT-SA-2020SA164505			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukocytosis; Pyrexia	Clopidogrel Bisulfate			S	Oral	75 Mg, Qd		Sanofi
	Fondaparinux Sodium			S	Subcutaneous	2.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Intravenous (not otherwise specified)			Sanofi
	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	250 Mg		Not Reported
	Methylprednisolone			S	Unknown	1 Mg/Kg		Not Reported
	Tirofiban			S	Intravenous bolus	25 Mg/Kgbody		Not Reported
	Tirofiban			S	Intravenous (not otherwise specified)	0.15 Mg/Kgbody Per Minute For 48 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17967607	EXPEDITED (15-DAY)		HO, OT	MX-ADVANZ PHARMA-202006006683			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Venous Occlusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Q12h		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17970174	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200635837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported

Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Arava	C	Oral	Not Reported
Plaquenil	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Simponi	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17970195	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200635760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17970197	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200635877		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17970200	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200635860			Female	CAN

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

Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Remicade		S	Intravenous (not otherwise specified)	Janssen
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17974266	EXPEDITED (15-DAY)		DS	CA-ROCHE-1895807		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 731.0		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Therapy Duration: 365.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Sulfate]			
	Acetaminophen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Ergocalciferol	C		Not Reported
	Lansoprazole	C	Unknown	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
	Salmon Oil	C		Not Reported
	Glucosamine	C		Not Reported
	Salazopyrina	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17996560	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-206515		75 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17996562	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-206518		38 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17996581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797530		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997199	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252622		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective For Unapproved Indication; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Sun
	Enoxaparin Sodium			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997208	EXPEDITED (15-DAY)		DE, LT, OT	ES-AUROBINDO-AUR-APL-2020-033461		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	500 Milligram, Once A Day (Iv)		Aurobindo
	Dolquine			S	Unknown	800 Mg One Day, 400 Mg 4 Days		Not Reported
	Kaletra			S	Unknown	532 Mg/133.2 Mg/Dia		Not Reported
	Digoxin			S	Unknown	0.5 Milligram(Iv)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997217	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2964225-00		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Splenectomy; Swelling; Therapeutic Product Effect Decreased	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997275	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054654			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	567.0 Milligram, Qmo		Not Reported
	Arava			S	Unknown	20.0 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15.0 Milligram, Qwk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997803	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3474467-00		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997947	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3897		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997976	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252568		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Lupus Pneumonitis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Mycophenolic Acid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997985	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-		63 YR	Male	USA

2020R1-252620

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Pyridostigmine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17997989	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252621		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Hydroxychloroquine			S				Sun
	Methotrexate			S	Unknown	20 Milligram, Weekly		Sun
	Methotrexate			S				Sun
	Oseltamivir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17998469	EXPEDITED (15-DAY)		HO	FR-ACCORD-188793			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S		500 Mg On Day One, Followed By 250 Mg Per Day For The Next Four Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999321	EXPEDITED (15-DAY)		OT	NVSC2020ES188299		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatitis; Hypertriglyceridaemia	Ceftriaxona			S	Intravenous (not otherwise specified)	1 G, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Q12h		Not Reported
	Kaletra			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999378	EXPEDITED (15-DAY)		HO	NVSC2020ES188331		76 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	300 Mg, Q24h (200 Mg (1-0-0.5))		Novartis
	Imurel			S	Oral	50 Mg, Q24h 1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999446	EXPEDITED (15-DAY)		LT, OT	NVSC2020ES190183		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Disorientation; Hyperbilirubinaemia; Liver Function Test Abnormal; Urinary Retention	Hydroxychloroquine			S	Oral	Unk (800 Mg 1 Dia + 400 Mg El Resto)		Novartis
	Levofloxacin			S	Unknown	Unk (500 Mg/12 Horas)		Not Reported
	Lopinavir + Ritonavir			S	Unknown	Unk (200/20 Cuatro Veces Al Dia)		Not Reported
	Omeprazol			C	Unknown	Unk		Not Reported
	Pulmicort			C	Unknown	2 Puff Cada 8 Horas		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported
	Urbason			C	Unknown	Unk (40 Mg Primero Cada 8 Horas, A Los 5 Dias		Not Reported

	Clexane	C	Unknown	Cada 12) Unk (40/24 Horas)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999598	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999624	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009775			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypertension; Latent Tuberculosis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Calcium Gluconate			C	Oral			Not Reported
	Ezetimibe			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported

	Prasugrel Hydrochloride	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tamsulosin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999655	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Topical	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Topicort [Desoximetasone]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999711	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C	Unknown	500 Milligram, 2 Every 1 Day		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999724	EXPEDITED (15-DAY)		OT	CA-ACCORD-189321		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronic Acid	S	Unknown	Not Specified	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999726	EXPEDITED (15-DAY)		OT	CA-ACCORD-189320		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Accord
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999732	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Male	CAN

BMS-2020-054765

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999741	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1062470		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Off Label Use	Azithromycin			S	Unknown	Unk		Not Reported
	Kaletra			S	Oral	4 Dosage Form, Qd		Mylan
	Ceftriaxona /00672201/			S	Unknown	Unk		Mylan
	Dolquine			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999886	NON-EXPEDITED			US-PFIZER INC-2020261595		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metoclopramide Hcl			S		Unk		Pfizer
	Bactrim			S		Unk		Not Reported

	Plaquenil	S	Unk	Not Reported
	Codeine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000239	NON-EXPEDITED			US-MYLANLABS-2020M1059183			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use Complaint; Wrong Technique In Product Usage Process	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	Taking The Product For Three Days, Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000284	EXPEDITED (15-DAY)		HO, LT	CA-ACCORD-188459			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Ilaris		S	Subcutaneous	Not Reported
	Minocycline		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000285	EXPEDITED (15-DAY)		DS	CA-ACCORD-189366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Fatigue; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Accord
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			C				Not Reported
	Diclofenac			C				Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Indocid			C		Not Specified		Not Reported
	Leflunomide			C	Oral			Not Reported
	Naproxen			C		Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000286	EXPEDITED (15-DAY)		OT	CA-ACCORD-189580		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord
	Apo-Metoprolol			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Cimzia			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S		Frequency: 1 Every 1 Weeks		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S				Not Reported
	Metoprolol			S				Not Reported
	Naproxen			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Rosuvastatin			C				Not Reported
	Naproxen			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000287	EXPEDITED (15-DAY)		OT	CA-ACCORD-189581		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Methotrexate			S				Accord
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000365	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053832			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported

	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000802	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798067		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Codeine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Actavis
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Actavis
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Ramipril			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown	7 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen/Caffeine/Codeine Phosphate			C	Unknown			Not Reported
	Acetaminophen;Caffeine			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000818	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Ramipril			S	Oral			Actavis
	Ramipril			S	Oral			Actavis
	Dorzolamide Hydrochloride W/Timolol Maleate			S	Unknown			Actavis
	Dorzolamide Hydrochloride W/Timolol Maleate			S	Unknown	2 Dosage Forms Daily;		Actavis
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000827	EXPEDITED (15-DAY)		DE, LT	ES-PFIZER INC-2020260705		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Azithromycin			S		500 Mg, Daily		Pfizer
	Kaletra			S		532/133.2 Mg/ Day		Not Reported
	Levofloxacin			S	Intravenous (not otherwise specified)	500 Mg, Daily		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	0.5 Mg		Not Reported
	Dolquine			S		800 Mg For One Day		Not Reported

	Dolquine	S	400 Mg For 4 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000883	EXPEDITED (15-DAY)		OT	NVSC2020ES186825		59 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Long Qt Syndrome	Azitromicina			S	Oral	Unk		Novartis
	Dolquine			S	Oral	Unk (30 Comprimodos)		Not Reported
	Kaletra			S	Oral	2 Df, Q12h (120 Comprimidos)		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001046	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1797238		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic	Naproxen			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported

Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Lasix [Furosemide]		C		Not Reported
	Naproxen		C		Not Reported
	Oxycontin		C	Unknown	Not Reported
	Oxyneo		C	Unknown	Not Reported
	Acetaminophen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001266	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2020SE84997		90 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Quetiapine			S	Oral			Zeneca
	Cobicistat			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Darunavir			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001332	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054631		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Oral		Not Reported
	Tocilizumab		S	Subcutaneous		Not Reported
	Prednisone		C	Unknown	30 Milligram, Qd	Not Reported
	Methotrexate		C	Unknown	25 Milligram, Qwk	Not Reported
	Desoximetasone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001384	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1797356			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Oral			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001386	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1797203		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral	2.6 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone			S	Other			Not Reported
	Triamcinolone Hexacetonide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001388	EXPEDITED (15-DAY)		HO, OT	ES-FRESENIUS KABI-FK202006889		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperglycaemia; Mania; Off Label Use; Renal Failure	Methylprednisolone (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care
	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Ritonavir/Lopinavir			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001392	EXPEDITED (15-DAY)		HO	NVSC2020ES188340		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxona			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001396	EXPEDITED (15-DAY)		OT	NVSC2020ES186826		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder	Hydroxychloroquine Sulfate			S	Oral	Unk		Novartis
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Q12h (120 Comprimidos)		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001467	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Millilgram 2 Every 1 Days	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001472	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Morphine			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Oral			Not Reported
	Bisoprolol			S	Unknown			Duramed
	Methotrexate			S	Unknown			Barr
	Zopiclone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Teva
	Zantac			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054755			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001656	EXPEDITED (15-DAY)		HO	IT-GILEAD-2020-0480803		90 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Cobicistat			S	Oral	150 Mg, Qd		Gilead
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Darunavir			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001890	EXPEDITED (15-DAY)		OT	CA-ACCORD-189076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Prescribed Underdose; Product Use Issue	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone/Prednisone Acetate			C	Unknown	Not Specified		Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001901	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054813		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

Acetaminophen	C	Unknown	Unk		Not Reported
Arava	C	Unknown			Not Reported
Calcium Carbonate	C	Unknown			Not Reported
Cymbalta	C	Unknown			Not Reported
Elavil [Allopurinol]	C	Unknown			Not Reported
Hydrochlorothiazide	C	Unknown	Unk		Not Reported
Imitrex [Sumatriptan]	C	Unknown			Not Reported
Lyrica	C	Unknown			Not Reported
Premarin	C	Unknown			Not Reported
Sumatriptan Succinate	C	Unknown			Not Reported
Tenormin	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18002234	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798053		74 YR	Female	CAN

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

	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Levothyroxine	S	Unknown		Not Reported
	Levothyroxine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Ramipril	S	Unknown	1 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C			Not Reported
	Acetaminophen;Caffeine	C			Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Caffeine;Codeine;Paracetamol	C			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram Daily;	Not Reported
	Methylprednisolone	C			Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18002263	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798014		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin	Morphine Sulfate			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Actavis
	Asa			S	Unknown			Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Teva

Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Fosinopril	S	Unknown		Teva
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Synthroid	S	Unknown		Not Reported
	Vitamin D[Colecalciferol]	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Tylenol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004401	EXPEDITED (15-DAY)		OT	NVSC2020ES186313		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Interferon Beta-1b			S	Subcutaneous	30 Ug, Qd		Novartis
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Qd		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400 Mg, Qd		Not Reported
	Interferon Beta-1a			S	Subcutaneous	30 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004450	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-22056			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Infliximab			S	Unknown			Not Reported

Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab	S	Subcutaneous	Unknown		Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen Sodium	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004519	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053789		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported

Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Methotrexate	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18005350	EXPEDITED (15-DAY)		OT	NVSC2020ES186788		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxychloroquine Sulfate			S	Oral	Unk		Novartis
	Azitromicina			S	Oral	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18005408	EXPEDITED (15-DAY)		OT	NVSC2020US190331		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Product Use In Unapproved Indication	Hydroxychloroquine			S	Other	400 Mg, Bid		Novartis
	Hydroxychloroquine			S	Other	200 Mg, Bid		Novartis
	Cefepime			S	Intravenous (not otherwise specified)	2 G, Q8h		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18006104	EXPEDITED (15-DAY)		OT	NVSC2020ES186955		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia; Long Qt Syndrome	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Q12h		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Q12h		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Q12h		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Q12h		Novartis
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Df, Q12h		Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Df, Q12h		Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Df, Q12h		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported
	Telmisartan/Hydrochlorothiazide			C	Oral	80 Mg, Qd		Not Reported
	Metformina			C	Oral	850 Mg, Q8h		Not Reported
	Tocilizumab			C	Unknown	600 Mg, Once/Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18006107	EXPEDITED (15-DAY)		OT	NVSC2020ES183569		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Hydroxychloroquine Sulfate			S	Oral	1 Df, Q12h (400 Mg C/12 Horas Seguido De 200 Mg C/12 Horas)		Novartis
	Hydroxychloroquine Sulfate			S				Novartis
	Azithromycin			S	Oral	500 Mg, Qd (500 Mg Cada 24h)		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona			S	Unknown	Unk (No Especificada)		Not Reported
	Ceftriaxona			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Q12h (120		Not Reported

					Comprimidos (Blister))	
	Lopinavir/Ritonavir	S				Not Reported
	Parizac	C	Unknown	Unk (28 Capsulas)		Not Reported
	Carduran	C	Unknown	Unk (28 Comprimidos)		Not Reported
	Atacand	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	11182943	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015191806		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Enbrel			S	Unknown	50 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	2.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	2.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Celebrex			S	Unknown	50 Mg, Qwk		Pfizer
	Celebrex			S				Pfizer
	Sulfasalazine			S	Unknown	2 G, Qd		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 Mg, Unk		Pfizer
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S			Not Reported
Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
Orencia	S		250 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Unknown	300 Mg, Unk	Not Reported
Plaquenil	S	Unknown	300 Mg, Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Mg, Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	12130379	EXPEDITED (15-DAY)		OT	CA-ROCHE-1717281			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Drug Intolerance; Drug Tolerance Decreased; Intentional Product Use Issue; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Onychoclasis; Synovitis; Tooth Loss	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Zostavax	S	Unknown	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cortisone	C	Oral	Not Reported
	Voltaren [Diclofenac]	C	Unknown	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

	Desoximetasone	C	Unknown	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	12328394	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016213277		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Condition Aggravated; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S		50 Milligram, Qwk		Unknown
	Enbrel			S		Unk		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Pfizer
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Estradiol	C	Unknown	0.6%, 3x/Day	Not Reported
Estradiol	C	Unknown	Unk	Not Reported
Furosemide	C	Unknown	40 Mg, Qd	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	320 Mg, Qd	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Xalatan	C	Ophthalmic	50 Mg, Qd	Not Reported
Xalatan	C	Unknown	Unk	Not Reported
Xalatan	C		50 Ug, 1x/Day	Not Reported
Xalatan	C		Unk, Solution Opthalmic	Not Reported
Dorzolamide Hcl/Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
Baclofen	C		10 Mg, 2x/Day	Not Reported
Baclofen	C			Not Reported
Levaquin	C		500 Mg, Qd For 10 Days	Not Reported
Levaquin	C		Unk	Not Reported
Levaquin	C		Unk	Not Reported
Morphine	C		Unk	Not Reported
Potassium Chloride	C		1500 Mg, Qd	Not Reported
Potassium Chloride	C	Unknown	Unk	Not Reported
Zingiber Officinale	C	Unknown	500 Mg, Unk	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
Estrogel	C	Unknown	0.6%, 3x/Day	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	500 Milligram, Qd	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Prednisone	C		5 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	12736125	NON-EXPEDITED			US-PFIZER INC-2016421350		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Scratch; Hypoacusis; Impaired Healing; Therapeutic Product Effect Incomplete	Xeljanz			S		5 Mg		Pfizer
	Xeljanz			S		10 Mg		Pfizer
	Xeljanz			S		5 Mg		Pfizer
	Hydroxychloroquine			S		200 Mg		Not Reported
	Duloxetine			S		30 Mg		Not Reported
	Vitamin D2			S		50000 Iu, Weekly		Not Reported
	Alendronate			S		70 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	13064952	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161217720			Female	CAN

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

	Pertussis Vaccine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	13109188	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105848			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	13245840	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1026		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Celebrex			S	Oral	As Required		Not Reported

Therapy Non-Responder; Viral Upper Respiratory Tract Infection	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituximab	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	13319241	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902165		55 YR	Female	CAN

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

	Sulfasalazine			S	Unknown					Not Reported
	Apo-Azathioprine			S	Unknown					Not Reported
	Apo-Azathioprine			S	Unknown					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Minocycline Hydrochloride			S	Unknown					Not Reported
	Xeljanz			S	Unknown					Not Reported
	Leflunomide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	13875457	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2015-0556		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Product Complaint; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	14567043	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016281698		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not	640 Mg, Cyclic(640		Not Reported

Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain				otherwise specified)	Milligram, Q4wk)	
	Orencia		S	Subcutaneous	125 Mg, Qwk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz		C	Oral	5 Milligram, Qd	Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day	Not Reported
	Hydroxychloroquine		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	14639970	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0752		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Overdose; Product Use Issue; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Leflunomide		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	15327973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176030		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Unknown			Not Reported

	Otezla	S	Oral		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Minocin	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	C	Unknown	Therapy Duration: 4 Years	Not Reported
	Methotrexate Sodium	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Abatacept	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	15619732	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105993			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	15680068	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3490		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name			S	Subcutaneous			Not Reported

Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Thyroid Neoplasm; Toxicity To Various Agents	Unknown)			
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported

Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Actemra	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	15707673	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584580-00		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	15929079	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832232		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	16101730	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190316870		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Failure; Urticaria; Wrist Surgery	Arava	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	16898012	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019429767		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Cataract; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1 Every 1 Week		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)			Pfizer
	Actemra			S	Subcutaneous	160 Mg, 1 Every 1 Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Synovial Cyst; Synovitis; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; Viral Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	80 Mg, 1x/Day	Not Reported
	Diclofenac	C		Unk	Not Reported
	Pantoprazole Magnesium	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17390882	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018169790		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug	Enbrel			S		50 Mg, Weekly		Pfizer

Intolerance; Fatigue; Off Label Use	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Enbrel	S		50 Mg, 1x/Day	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	50 Milligram, Bid	Pfizer
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ciclosporin	S		Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cosentyx	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Methotrexate Sodium	C		25 Mg, Weekly	Not Reported
	Hydroxychloroquine	C		200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17394673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537374		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Multiple Allergies; Musculoskeletal Pain; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17517039	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200243785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Uveitis	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Piroxicam			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Codeine	C	Unknown	Not Reported
	Codeine	C	Subcutaneous	Not Reported
	Imuran /00001501/	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17554482	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022709		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	1 Dosage Form		Bristol Myers Squibb
	Triamcinolone			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular			Bristol Myers Squibb
	Triamcinolone Acetonide			S				Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported

Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Anakinra	S	Unknown	50 Milligram	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Anakinra	S	Subcutaneous	1 Dosage Form	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	4 Dosage Form, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	1 Dosage Form, Qd	Not Reported
	Immune Globulin Iv	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin Iv	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Intravenous (not	3 Milligram/Kilogram	Not Reported

		otherwise specified)		
Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q6wk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Infliximab	S	Unknown	1 Dosage Form, Qd	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
Naproxen	S	Unknown		Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	50 Milligram, Bid	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported
Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
Tocilizumab	S			Not Reported
Triamcinolone Hexacetonide	S	Other		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported

	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17559938	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1439		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17672252	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413057		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17697005	EXPEDITED (15-DAY)		DS, OT	MX-ADVANZ PHARMA-202004003548			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17743409	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437160		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; C-Reactive Protein Abnormal; Contraindicated Product	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Administered; Depression; Dermatitis Allergic; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Hypersensitivity; Inflammation; Intervertebral Disc Protrusion; Joint Injury; Liver Disorder; Malaise; Nausea; Nerve Block; Pruritus; Pruritus Allergic; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Infliximab	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Cetirizine Hydrochloride	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Gabapentin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17747073	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported

Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Ketoprofen	C		Not Reported
	Naproxen	C		Not Reported
	Omeprazole	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17747156	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437151		53 YR	Female	CAN

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

Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)		Janssen
	Azathioprine	S	Unknown		Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown		Not Reported
	Clavulin /00756801/	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Amoxicillin Sodium And Potassium Clavulanate	S	Unknown		Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Spektramox	S			Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Plaquenil /00072603/	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tridural	C	Unknown	Prolonged-Release	Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17754231	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180836875		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Remicade			S	Intravenous (not otherwise specified)			Janssen

Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Levothyroxine Sodium	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Oral	Not Reported
	Codeine Phosphate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Cosopt	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Ramipril	S	Unknown	Not Reported
	Imuran /00001501/	S	Unknown	Not Reported
	Levothyroxine	S	Subcutaneous	Not Reported
	Dorzolamide	C	Ophthalmic	Not Reported

Hydrochloride/Timolol Maleate			
Dorzolamide	C	Ophthalmic	Not Reported
Hydrochloride/Timolol Maleate			
Dorzolamide	C	Ophthalmic	Not Reported
Hydrochloride/Timolol Maleate			
Codeine Phosphate W/Paracetamol	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Tylenol 2	C	Unknown	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C		Not Reported
Caffeine	C		Not Reported
Hydroxychloroquine Phosphate	C		Not Reported
Acetaminophen W/Codeine Phosphate	C	Intravenous (not otherwise specified)	Not Reported
Meprobamate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17755120	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593218		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17810521	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)			
				Remicade	S	Intravenous (not otherwise specified)			Not Reported
				Remicade	S	Intravenous (not otherwise specified)			Not Reported
				Hydroxychloroquine	S	Unknown			Not Reported
				Hydroxychloroquine Sulfate	S	Unknown			Not Reported
				Methotrexate	S	Intramuscular			Not Reported
				Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17844977	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2606882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported

Enbrel	S	Subcutaneous	Not Reported
Gold	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Risedronate Sodium	S	Oral	Not Reported
Risedronate Sodium	S	Unknown	Not Reported
Risedronic Acid	S	Unknown	Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17880505	EXPEDITED (15-DAY)		OT	NVSC2020US160714			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Pulmonary Alveolar Haemorrhage	Hydroxychloroquine			S	Transplacental	Maternal Dose:Unk		Novartis
	Ceftriaxone			S	Transplacental	Maternal Dose: Unk		Not Reported
	Azithromycin			S	Transplacental	Maternal Dose:Unk		Not Reported
	Betamethasone			S	Transplacental	Matrenal Dose:Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17881154	EXPEDITED (15-DAY)		OT	NVSC2020US160715			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unk		Novartis
	Ceftriaxone			S	Transplacental	Maternal Dose: Unk		Not Reported
	Azithromycin			S	Transplacental	Maternal Dose: Unk		Not Reported
	Betamethasone			S	Transplacental	Maternal Dose:Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17881253	EXPEDITED (15-DAY)		HO	NVSC2020US160711		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication; Tachypnoea	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Betamethasone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17900590	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200616230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Ciclosporine			S	Oral			Not Reported
	Ciclosporine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Imuran /00001501/	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17918262	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017342		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine			S	Oral			Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	1 Df, Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Calcium			C	Unknown	500 Mg, Qd		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Q.Wk.		Not Reported
	Estrogel			C	Unknown	0.6 %, Tid		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported
	Jamp K20			C	Unknown	1500 Mg, Qd		Not Reported

Valsartan	C	Unknown	320 Mg, Qd		Not Reported
Xalatan	C	Unknown	50 Mg, Qd		Not Reported
Xalatan	C	Ophthalmic	Unk		Not Reported
Gravol	C	Unknown	Unk		Not Reported
Estradiol	C	Unknown	0.6 %, Tid		Not Reported
Potassium Chloride	C	Unknown	Unk		Not Reported
Baclofen	C	Unknown	Unk		Not Reported
Levaquin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17922728	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021694		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17925830	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200624738		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Azathioprine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Venlafaxine Hydrochloride	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17925842	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200625740			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17968840	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200636012		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18001912	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252582		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Sun
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18001917	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252626		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Azithromycin			S				Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Hydroxychloroquine			S				Ipca
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18003248	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-253136		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Azithromycin			S	Unknown	Unk		Sun
	Dexamethasone			S	Unknown	Unk		Sun
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18003866	EXPEDITED (15-DAY)		OT	JO-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252634		30 YR	Female	JOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Live Birth; Premature Labour	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18004091	EXPEDITED (15-DAY)		OT	ES-ROCHE-2637937		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Off Label Use; Product Use In Unapproved Indication	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18004472	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054652		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	100 Milligram, 1 Every 2 Days		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18004655	EXPEDITED (15-DAY)		OT	CA-ACCORD-189614		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Methotrexate			S		Therapy Duration: 365		Not Reported
	Hydroxychloroquine			S				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18005024	EXPEDITED (15-DAY)		OT	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-053035			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Zydus Pharm
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Zydus Pharm
	Azithromycin			S	Unknown	Unk		Zydus Pharm
	Propofol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18005119	EXPEDITED (15-DAY)		OT	CA-ACCORD-189639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Leflunomide			S				Not Reported
	Cimzia			S		Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Tocilizumab	S			Not Reported
	Tofacitinib	S			Not Reported
	Xeljanz	S			Not Reported
	Sulfasalazine	S			Not Reported
	Rabeprazole	C	Oral		Not Reported
	Methotrexate	S	Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18005142	EXPEDITED (15-DAY)		OT	CA-ACCORD-189583		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Novo-Rythro			S				Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Erythromycin			S				Not Reported
	Actonel			S				Not Reported
	Enbrel			S				Not Reported
	Celebrex			C				Not Reported
	Cannabis Sativa			C				Not Reported
	Bupropion/Bupropion Hydrochloride			C				Not Reported
	Wellbutrin			C		1 Every 1 Days		Not Reported
	Ergocalciferol			C				Not Reported
	Hydroxychloroquine			C	Oral	1 Every 1 Days		Not Reported
	Wellbutrin			C				Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Ergocalciferol			C		1 Every 1 Days		Not Reported
	Celebrex			C		2 Every 1 Days		Not Reported

	Actonel			S	Oral	1 Every 1 Weeks				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18005333	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054749			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18005632	EXPEDITED (15-DAY)		OT	NVSC2020ES188704		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Atorvastatin			S	Oral	40 Mg, Qd		Novartis

	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Kaletra	S	Oral	4 Df, Q3mo	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18005647	EXPEDITED (15-DAY)		OT	NVSC2020ES187890		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Q12h		Novartis
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Q24h		Not Reported
	Levofloxacin			S	Oral	500 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Q12h		Not Reported
	Novorapid			C	Subcutaneous	10 Iu, Q8h		Not Reported
	Oseltamivir			C	Oral	75 Mg, Q6h		Not Reported
	Piperacillin+Tazobactam			C	Intravenous (not otherwise specified)	1 Df, Q8h		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Mg, Once/Single		Not Reported
	Losartan			C	Oral			Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Mg, Q24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006184	EXPEDITED (15-DAY)		HO	NVSC2020FR193516		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006350	EXPEDITED (15-DAY)		HO, OT	FR-BION-008838			Unknown	FRA

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

Atrial Flutter; Product Use In Unapproved Indication	Azithromycin		S		500 Mg On Day One, Followed By 250 Mg Per Day For The Next Four Days	Not Reported
	Hydroxychloroquine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006759	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-189771		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 24 Hours		Not Reported
	Sulfasalazine			S	Oral	1 Every 24 Hours		Not Reported
	Myochrysine			S	Intramuscular	1 Every 3 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Paracetamol			C				Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			C	Unknown	2 Every 1 Days		Not Reported
	Diphenoxylate			C	Unknown	1 Every 24 Hours		Not Reported
	Pantoprazole			C	Unknown	1 Every 24 Hours		Not Reported
	Actonel			C	Unknown	1 Every 1 Weeks		Not Reported

Iron	C	Unknown	1 Every 24 Hours		Not Reported
Prednisone	C	Unknown	1 Every 24 Hours		Not Reported
Loperamide	C	Unknown			Not Reported
Ergocalciferol	C	Unknown	1 Every 24 Hours		Not Reported
Nasonex	C	Unknown	2 Every 1 Days		Not Reported
Trazodone	C	Unknown	1 Every 24 Hours		Not Reported
Tylenol	C	Unknown	1 Every 24 Hours		Not Reported
Nasonex	C	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006777	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252856		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Serotonin Syndrome	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Lopinavir/Ritonavir			S	Unknown	400/100mg, Bid		Not Reported
	Morphine			S	Unknown	3 Milligram, Qd		Ranbaxy
	Risperidone			S	Unknown	1 Milligram, Bid		Ranbaxy
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006809	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055196			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Sulfasalazine		S	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18007000	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021492		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18007304	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055245			Female	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia		S	Unknown	Bristol Myers Squibb
	Actemra		S	Subcutaneous	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18007323	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-03178		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Muscular Weakness; Somnolence; Suicide Attempt; Toxicity To Various Agents; Ventricular Tachycardia	Hydroxychloroquine Sulfate Tablets			S	Oral	20 Dosage Form (Intentional Overdose)		Lupin
	Methotrexate			S	Oral	30 Dosage Form (Intentional Overdose)		Not Reported
	Prednisone			S	Unknown	30 Dosage Form (Intentional Overdose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18007846	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054730		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody	Orencia			S	Unknown			Bristol Myers Squibb

Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18008613	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051317		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Peripheral Swelling; Somnolence; Visual Impairment	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Acetaminophen			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S		5 Mg, Weekly (Qw)		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Enbrel			S		50 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S		40 Milligram, Weekly (Qw)		Not Reported
	Diphenhydramine Hydrochloride W/Paracetamol			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Apo-Leflunomide			S		20 Mg, Once Daily (Qd)		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		200 Mg, Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, 2x/Day (Bid)	Not Reported
	Tylenol [Paracetamol]	S		2000 Milligram	Not Reported
	Apo-Acetaminophen	S		325 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Meloxicam	C			Not Reported
	Methotrexate	C		Unk, Weekly (Qw)	Not Reported
	Tofacitinib	C			Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Synthroid	C			Not Reported
	Celebrex	C			Not Reported
	Hydromorphone Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18009358	EXPEDITED (15-DAY)		DE	CA-BAUSCH-BL-2020-019569		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Metformin			S	Oral			Santarus
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Atrovent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported

	Furosemide	S	Unknown	Not Reported
	Ipratropium Bromide/Salbutamol Sulfate	S	Unknown	Not Reported
	Lipitor	S	Unknown	Not Reported
	Losec	S	Oral	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18009629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	420 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Timolol Maleate			C	Ophthalmic	Unk, Bid		Not Reported
	Ramipril			C	Unknown			Not Reported
	Prednisone			C	Unknown	7 Milligram, Qd		Not Reported
	Meprobamate			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Dorzolamide Hydrochloride			C	Ophthalmic	Unk, Bid		Not Reported

Codeine	C	Unknown	Not Reported
Caffeine	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18009957	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054789		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010233	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052299			Unknown	CAN

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

Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Enbrel	S	Subcutaneous	25 Milligram		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Prednisone	S	Oral	3 Milligram, Bid		Not Reported
	Prednisone	S	Oral	5 Milligram, Bid		Not Reported
	Naproxen	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010295	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2073		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010316	EXPEDITED (15-DAY)		OT	NVSC2020ES186804		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea	Azithromycin			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Q12h		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010328	EXPEDITED (15-DAY)		OT	NVSC2020ES186909		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Novartis
	Dolquine			S	Oral	400 Mg, Qd (Comprimidos Recubiertos, 30 Comprimidos)		Not Reported
	Kaletra			S	Oral	4 Df, Qd (Comprimidos Recubiertos Con Pelicula, 120 Comprimidos)		Not Reported
	Ceftriaxona			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010333	EXPEDITED (15-DAY)		OT	NVSC2020IT191070		33 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticaria	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Cefixime			S	Oral	400 Mg, Qd		Not Reported

	Plaquenil		S	Oral	400 Mg, Qd	Not Reported
	Deltacortene		S	Oral	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010551	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009794		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Finger Deformity; Hepatic Enzyme Increased; Hepatic Fibrosis; Insomnia; Lower Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Pain; Rash; Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Effexor Xr			S	Oral			Not Reported
	Venlafaxine Hcl			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Reactine			C	Unknown			Not Reported
	Cetirizine			C				Not Reported
	Ultram [Tramadol Hydrochloride]			C	Unknown			Not Reported
	Zopiclone			C	Unknown	7.5 Milligram, Qhs (Bedtime)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010561	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009813			Female	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Endocervical	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010656	EXPEDITED (15-DAY)		OT	CA-ROCHE-2638269		58 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010712	EXPEDITED (15-DAY)		OT	NVSC2020CA193395			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Stiffness; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Neoral			S	Unknown	125 Mg, Bid		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	150 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Prednisone			C	Unknown	10 Mg		Not Reported
	Citalopram Hydrobromide			C	Unknown	1 Df, Qw		Not Reported
	Citalopram Hydrobromide			C	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010734	EXPEDITED (15-DAY)		DE	NVSC2020IT195079			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Product Use In Unapproved Indication	Azithromycin			S	Unknown	500 Mg, Qd		Novartis
	Ceftriaxone			S	Unknown	2 Gr (For 6 Days)		Not Reported
	Lopinavir,Ritonavir			S	Unknown	400/100 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Enoxaparin			S	Subcutaneous	4000 Ui (Once A Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010937	EXPEDITED (15-DAY)		HO	NVSC2020IR190308		50 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Product Use In Unapproved Indication; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Kaletra			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Imipenem			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010941	EXPEDITED (15-DAY)		OT	NVSC2020ES188743		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Qd (200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimidos)		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010950	EXPEDITED (15-DAY)		HO	NVSC2020IR190300		57 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Product Use In Unapproved Indication; Treatment Failure	Hydroxychloroquine			S	Unknown			Novartis
	Kaletra			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

	Mycophenolic Acid	C	Unknown	Not Reported
	Cyclosporine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010951	EXPEDITED (15-DAY)		OT	NVSC2020ES186921		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd (2 G Cada 24 H)		Not Reported
	Ceftriaxona			S				Not Reported
	Lopinavir + Ritonavir			S	Oral	1 Df, Q12h (Accord)		Not Reported
	Lopinavir + Ritonavir			S				Not Reported
	Bufomix			C	Unknown	Easyhaler 320 Microgramos//9 Microgramos/Inhalacion Polvo Para Inhalacion		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Condrosan			C	Unknown	Unk (Capsulas Duras)		Not Reported
	Vesicare			C	Unknown	Unk (Comprimidos Recubiertos Con Pelicula)		Not Reported
	Prednisona			C	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	Unk (Comprimido)		Not Reported
	Axiago			C	Unknown	Unk (Comprimidos Gastrorresistentes)		Not Reported
	Atorvastatina			C	Unknown	Unk (Comprimido)		Not Reported
	Lyrica			C	Unknown	Unk (Capsulas Duras)		Not Reported
	Clexane			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk (Comprimido)		Not Reported
	Sintrom			C	Unknown	Unk (Comprimidos)		Not Reported
	Movalis			C	Unknown	Unk (Capsulas)		Not Reported

Doclis	C	Unknown	Unk		Not Reported
Rivotril	C	Unknown	Unk (Comprimidos)		Not Reported
Montelukast	C	Unknown	Unk (Comprimido)		Not Reported
Optovite B12	C	Unknown	Unk (1.000 Microgramos Solución Inyectable)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010958	EXPEDITED (15-DAY)		HO	NVSC2020IR190303		65 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Kaletra			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown			Not Reported
	Imipenem			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010959	EXPEDITED (15-DAY)		HO	NVSC2020IR190298		66 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Product Use In Unapproved Indication; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Kaletra			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Tavanic			S	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	17981265	EXPEDITED (15-DAY)		HO	NVSC2020IT183122		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash Morbilliform	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Roactemra			S	Unknown	1 Df, Qd		Not Reported
	Clexane			S	Subcutaneous	8000 Kiu, Qd		Not Reported
	Plaquenil			S	Oral	2 Df, Qd		Not Reported
	Fidato			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported
	Kaletra			S	Oral	4 Df, Qd		Not Reported
	Urbason Solubile Forte			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18010416	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-20K-028-3473484-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal;	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Tramacet	S	Oral	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Calcium Active	C	Unknown	Not Reported
	Depomedrol	C	Intra-articular	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lorazepam	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Metformin	C		Not Reported
	Methylprednisolone Acetate	C	Intra-articular	Not Reported
	Nortriptyline	C		Not Reported
	Nortriptyline	C		Not Reported
	Nortriptyline Hydrochloride	C		Not Reported
	Nortriptyline Hydrochloride	C		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Premarin	C	Unknown	Not Reported
	Risedronate Sodium	C		Not Reported
	Acetaminophen	C		Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18010475	EXPEDITED (15-DAY)		HO	NVSC2020ES188682		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hyperbilirubinaemia	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Novartis
	Azitromicina			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Df, Q12h		Not Reported
	Allopurinol			C	Oral	100 Mg, Qd		Not Reported
	Simvastatina			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18010514	EXPEDITED (15-DAY)		HO	NVSC2020CA194512		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18011088	EXPEDITED (15-DAY)		HO, OT	NVSC2020IR190317		64 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Product Use In Unapproved Indication; Treatment Failure	Hydroxychloroquine			S	Unknown			Novartis
	Kaletra			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Imipenem			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18011091	EXPEDITED (15-DAY)		OT	NVSC2020ES188746		68 YR	Male	ESP

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

Mixed Liver Injury	Azitromicina	S	Oral	500 Mg, Qd	Novartis
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
	Piperacilina + Tazobactam Sandoz	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfametoxazol + Trimetoprima	S	Oral	Unk	Not Reported
	Kaletra	S	Oral	2 Df, Qd	Not Reported
	Micafungin Sodium	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18011123	EXPEDITED (15-DAY)		HO	NVSC2020CA194518		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	14845152	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1364		37 YR	Female	CAN

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

Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Qwk	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Q2wk	Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Q2wk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Aleve	C	Unknown	As Needed	Not Reported
	Aleve	C	Unknown	As Needed	Not Reported
	Bupropion	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	15568789	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0818		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Swelling; Therapeutic Product Effect Incomplete;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times/Week, Cyclical		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Treatment Failure	Sulfasalazine	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Rituxan	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	16418876	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1768		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	17086848	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5744		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Cardiac Failure; Cytopenia; Generalised Oedema; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18011182	EXPEDITED (15-DAY)		OT	NVSC2020CA193398			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Neoral			S	Unknown	125 Mg, Bid		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Azathioprine			S	Subcutaneous	150 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported

	Citalopram Hydrobromide	C	Unknown	1 Df, Qw	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg	Not Reported
	Prednisone	C	Unknown	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18011283	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001503			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haematotoxicity; Hypokalaemia; Intentional Overdose; Somnolence; Suicide Attempt; Toxicity To Various Agents; Treatment Noncompliance; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	200 Milligram		Ipca
	Methotrexate			S	Oral	2.5 Milligram		Not Reported
	Prednisone			S	Oral	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18011299	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1798112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Morphine Sulfate			S	Unknown			Teva
	Acetaminophen			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	12.5 Milligram Daily;		Actavis
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18011300	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Bisoprolol			S	Unknown	12.5 Milligram Daily;		Duramed
	Calcium Carbonate			S	Unknown			Not Reported
	Ramipril			S	Unknown	12.5 Milligram Daily;		Actavis
	Magnesium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Buprenorphine			S	Unknown	10 Milligram Daily;		Not Reported
	Cyanocobalamin			S	Unknown			Not Reported
	Fish Oil			S	Unknown			Not Reported
	Furosemide And Potassium Chloride			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Magnesium Gluconate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pyridoxine Hydrochloride			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown	15 Milligram Daily;		Not Reported
	Vitamin B6			S	Unknown			Not Reported
	Vitamin D			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18011303	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1798139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Morphine			S	Unknown			Teva
	Acetaminophen			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	12.5 Milligram Daily;		Actavis
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18011311	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1798090		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica;	Codeine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Ramipril			S	Unknown	1 Dosage Forms Daily;		Actavis
	Dorzolamide Hydrochloridew/Timolol Maleate			S	Unknown			Actavis
	Dorzolamide Hydrochloridew/Timolol Maleate			S	Ophthalmic	2 Dosage Forms Daily;		Actavis

Treatment Failure	Dorzolamide Hydrochloridew/Timolol Maleate	S	Ophthalmic		Actavis
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Levothyroxine Sodium	S	Unknown	1 Dosage Forms Daily;	Not Reported
	Levothyroxine Sodium	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown	7 Milligram Daily;	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
	Acetaminophen;Caffeine	C	Unknown		Not Reported
	Caffeine	C	Unknown		Not Reported
	Diphenhydramine	C	Unknown		Not Reported
	Methylprednisolone	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Tylenol With Codeine	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18011482	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252579		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Tocilizumab			S	Unknown	80 Milligram, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	11437906	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056744		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Inflammation; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone		C	Unknown	10 Milligram	Not Reported
	Prednisone		C	Unknown	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	12864344	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1717965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Therapy Duration: 4 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral	Duration: 91.0 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	On 10/Feb/2016, She Received Last Dose Of Etanercept (Enbrel)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Duration: 183.0 Days		Not Reported

Pneumonia; Product Use Issue; Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Tylenol	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride	S	Oral		Not Reported
	Diphenhydramine Hydrochloride	S			Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydro	S	Unknown		Not Reported
	Apo-Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	S	Unknown	As Required	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg/Ml	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Amaryl	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Meloxicam	C			Not Reported
	Synthroid	C			Not Reported
	Tylenol	C			Not Reported
	Celebrex	C	Oral		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Glyburide	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Lipitor	C	Unknown		Not Reported

	Metformin	C		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Ramipril	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Percocet	C	Unknown	Not Reported
	Tylenol With Codeine No.3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	12913728	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091701			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoaesthesia; Infection; Nausea; Nephrolithiasis; Nerve Injury; Neutropenia; Osteoarthritis; Pain In Extremity; Paraesthesia; Product Use Issue; Pulmonary Congestion; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	40 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, 152.0 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk, 122 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Every One Week		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk, 580.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram, 580.0 Days		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Naprosyn E			S	Unknown	Unk		Not Reported

	Prednisone	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram (1 Every 2 Weeks)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	13030461	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2016CA1081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	12.5 Mg		Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	13602521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-047783		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	14124577	NON-EXPEDITED			US-PFIZER INC-2017459040		62 YR	Female	USA

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	14198688	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3639		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Endocervical			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Cyclical		Not Reported
	Remicade			S	Unknown			Not Reported
	Lyrica			C	Oral	50 Mg Am And 100 Mg Hs		Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	14495953	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15067530	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015912		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15067533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015880			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported

Loperamide	C	Oral	Unk		Not Reported
Pantoprazole	C	Unknown	Unk, Tid		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15101763	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016195			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	17 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Once Every 4 Weeks		Not Reported
	Orencia			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15103182	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of	Apo-Leflunomide			S	Other	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex

Personal Independence In Daily Activities; Therapeutic Response Decreased	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Apotex
	Actemra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Sulfasalazine	S	Unknown	2 G, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15333565	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst;	Leflunomide			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	160 Mg, Q.Wk.		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Unknown	80 Mg, Qd		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

Tenosynovitis; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15399793	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083448			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15556644	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018149424		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	160 Milligram		Not Reported
	Actemra			S	Unknown	162 Dosage Form		Not Reported

Decreased	Actemra	S	Unknown	162 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Imuran	C	Unknown	50 Milligram, Qd	Not Reported
	Azathioprine	C	Subcutaneous	50 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15570613	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018445765		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	50 Mg		Pfizer
	Rituximab			S	Unknown	Unk		Pfizer

Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown	160 Milligram	Not Reported
	Actemra	S	Unknown	162 Dosage Form	Not Reported
	Actemra	S	Unknown	162 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Tocilizumab	S		160 Mg, Unk	Not Reported
	Imuran	C	Unknown	50 Milligram, Qd	Not Reported
	Azathioprine	C	Subcutaneous	50 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15678194	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574920-00		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood	Humira			S	Subcutaneous			Not Reported

Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased; Colitis; Contraindicated Product Administered; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Oxygen Saturation Decreased; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Treatment Failure; Vitamin D Deficiency; Weight Decreased; Weight Increased	Humira	S	Subcutaneous		Not Reported
	Diamicron	S	Unknown		Not Reported
	Gliclazide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Asacol	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	225.0	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Norvasc	S	Oral		Not Reported
	Norvasc	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Aerius	C			Not Reported
	Crestor	C			Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Amlodipine Besilate	C	Unknown		Not Reported
	Atacand Plus	C			Not Reported

	Bisoprolol Fumarate	C		Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin D3	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Ebastine	C		Not Reported
	Januvia	C		Not Reported
	Pantoprazole	C		Not Reported
	Perindopril	C		Not Reported
	Tecta	C		Not Reported
	Trulicity	C		Not Reported
	Arava	C		Not Reported
	Perindopril Arginine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15716038	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587979-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15932037	EXPEDITED (15-DAY)		DS, HO	CA-ABBVIE-19K-028-2655672-00		48 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	15935541	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657057-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression;	Humira			S	Subcutaneous	Cyclical		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab;Vorhyaluronidase Alfa	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Reactine	C		Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	16252372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039070		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	776 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qcycle		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported

Infection	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qwk	Not Reported
	Methotrexate		C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate		C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Desoximetasone		C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		C	Unknown	400 Milligram, Qwk	Not Reported
	Xeljanz		C	Unknown	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	400 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	16839343	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-088706		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	10 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Milligram, 2 Every 1 Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	1000 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			S	Unknown	1 Milligram, Every 1 Day		Not Reported

Prednisone	S	Unknown	5 Milligram	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Q12h	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, 2 Every 1 Day	Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	2 Dosage Form, Qcycle	Not Reported
Asa	C	Unknown	325 Milligram	Not Reported
Bisoprolol	C	Unknown	5 Milligram, Every 1 Day	Not Reported
Endocet	C	Unknown	Unk	Not Reported
Endocet	C	Unknown	1 Dosage Form , 2 Every 1 Days	Not Reported
Folic Acid	C	Unknown	5 Milligram, Qcycle	Not Reported
Indomethacin [Indometacin]	C	Unknown	Unk	Not Reported
Macrogol	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	75 Milligram, 2 Every 1 Day	Not Reported
Naproxen Sodium	C	Unknown	1000 Milligram, Qcycle	Not Reported
Pennsaid	C	Topical	Unk	Not Reported
Vitamin B 12 [Vitamin B12 Nos]	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	12000 Milligram, Qd	Not Reported
Fish Oil	C	Unknown	12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	16949763	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437503		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Periarticular	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported

	Oxycodone	S	Unknown	Not Reported
	Periogard	S	Buccal	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Cetirizine	C	Unknown	Not Reported
	Desogestrel;Ethinylestradiol	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Paracetamol/Codeine	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Plaquenil	C		Not Reported
	Reactine (Canada)	C		Not Reported
	Tylenol With Codeine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17125243	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486138		70 YR	Female	CAN

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

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Sulfasalazine	S	Occlusive dressing technique	Not Reported
Xeljanz	C	Oral	Not Reported
Hydroxychloroquine	C		Not Reported
Methotrexate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17240944	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026890			Female	CAN

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

Adverse Drug Reaction; Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Leflunomide	S	Oral	20.0 Mg, Qd	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	0.5 Df, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Oral	3.0 G, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17350475	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004615			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mitral Valve Disease; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine Sodium			S	Unknown			Not Reported
	Bactrim			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17675841	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096882			Unknown	CAN

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

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate	S		200 Mg, Bid	Sanofi
	Arava	S		20 Mg, Qd	Sanofi
	Sulfasalazine	S		Unk	Not Reported
	Acetaminophen	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Codeine	C		Unk	Not Reported
	Leflunomide	C		20 Mg, Qd	Not Reported
	Meloxicam	C		Unk	Not Reported
	Methotrexate	C		Unk Unk, Qw	Not Reported
	Synthroid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17801314	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247202		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Midazolam			S	Unknown	Unk		Sun
	Midazolam			S				Sun
	Midazolam			S				Sun
	Azithromycin			S	Unknown	Unk		Sun
	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported

	Dolquine 200 Mg Comprimidos Recubiertos	S	Oral	200 Milligram, Bid	Not Reported
	Kaletra	S	Oral	Unk	Not Reported
	Ceftriaxona (501a)	S	Unknown	Unk	Not Reported
	Omnic Ocas 0,4 Mg Comprimidos De Liberacion Prolongada Recubiertos ...	C	Unknown	Unk	Not Reported
	Cortic - Corticoide	C	Unknown	Unk	Not Reported
	Manidon Hta 240 Mg Comprimidos De Liberacion Prolongada, 30 Comprim...	C	Unknown	Unk	Not Reported
	Rilast Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Polvo...	C	Unknown	Unk	Not Reported
	Simvastatina 20 Mg 28 Comprimidos	C	Unknown	Unk	Not Reported
	Kalpress 160 Mg Comprimidos Recubiertos Con Pelicula, 28 Comprimido...	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17806363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602172		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Orencia	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Gold	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Plaquenil Sulfate	C		Not Reported
Risedronate	C		Not Reported
Xeljanz	C	Oral	Not Reported
Cimzia	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17834708	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201903-000662			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Diarrhoea; Ocular Hypertension	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	4 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prograf			C		Unk		Not Reported
	Actonel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17857587	EXPEDITED (15-DAY)		HO, OT	RU-ADVANZ PHARMA-202005005933			Unknown	RUS

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

Exposure During Pregnancy; Iron Deficiency Anaemia; Placental Disorder; Placental Insufficiency; Pre-Eclampsia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	1 Df, Bid, 1 Tablet At Noon, 1 Tablet In The Evening	Concordia
	Clexane	S	Subcutaneous	0.4 Unk, Qd	Not Reported
	Clexane	S	Subcutaneous	0.4 Unk, Bid	Not Reported
	Clexane	S	Subcutaneous	0.4 Unk, Bid	Not Reported
	Prednisone	S	Unknown	Unk, Q3h (8 Times Daily)	Not Reported
	Methylprednisolone	S	Oral	8 Dosage Form, Qd	Not Reported
	Nifedipine	S	Unknown	30 Mg, Bid	Not Reported
	Nifedipine	S	Unknown	30 Mg, Qd	Not Reported
	Nifedipine	S	Unknown	30 Mg, Qd	Not Reported
	Nifedipine	S	Unknown	60 Mg In The Morning And 30 Mg In The Evening, Bid	Not Reported
	Methyldopa	S	Oral	0.5 Dosage Form, Qd	Not Reported
	Methyldopa	S	Oral	0.5 Dosage Form, Tid	Not Reported
	Methyldopa	S	Unknown	1.5 Dosage Form, Qid	Not Reported
	Methyldopa	S	Unknown	1.5 Dosage Form, Qid	Not Reported
	Omeprazole	S	Oral	1 Dosage Form, Bid	Not Reported
	Levothyroxine Sodium	S	Unknown	Unk	Not Reported
	Progesterone	S	Unknown	400 Mg, Qd, From 14 Weeks	Not Reported
	Azathioprine	S	Unknown	50 Mg, Qd In Morning	Not Reported
	Azathioprine	S	Unknown	50 Mg, Bid	Not Reported
	Prednisolone	S	Oral	4 Tablets In The Morning, 3 Tablets At Noon, 1 Tablet In The Evening	Not Reported
	Fosfomycin	S	Unknown	3 G, Hs	Not Reported
	Fosfomycin	S	Unknown	3.0 G, Qw, On Friday	Not Reported
	Dipyridamole	S	Unknown	75 Mg, Bid	Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Oral	1 Dosage Form, Tid	Not Reported
	Folic Acid	S	Oral	1 Dosage Form, Tid	Not Reported

Cefepime Hydrochloride	S	Intravenous (not otherwise specified)	An Unknown Dose Dosage With Sodium Chloride Solution 0.9%		Not Reported
Cefepime Hydrochloride	S		Unk		Not Reported
Magnesium Sulfate	S	Intravenous drip	Unk		Not Reported
Methylprednisolone	S	Intravenous drip	250.0 + Sodium Chloride Solution 0.9% - 100.0 Iv Drip Within 30 Min, Twice In A Week		Not Reported
Methylprednisolone	S	Intravenous drip	Solution 500.0 + Sodium Chloride Solution 0.9% - 100.0, 3 Iv Drip Within 30 Min, Twice In A Week		Not Reported
Ceftaroline Fosamil	S	Intravenous drip	600 Mg+ Sodium Chloride Solution 0.9% -100.0 Iv Drip Within An Hour		Not Reported
Suprastin	S	Oral	1 Df, In Evening		Not Reported
Suprastin	S	Oral	1 Dosage Form Twice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17880129	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP011746		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Diclofenac			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Rituxan	S	Unknown	Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17904229	EXPEDITED (15-DAY)		DS	CA-APOTEX-2020AP012166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Cyclosporine			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17907342	EXPEDITED (15-DAY)		OT	PHHY2019CA201811		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Unk	Not Reported
Methotrexate	C	Oral	20 Mg, Unk	Not Reported
Methotrexate	C	Oral	20 Mg, Unk	Not Reported
Methotrexate	C	Unknown	25 Mg, Qw	Not Reported
Hydroxychloroquine	C	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	C	Unknown	200 Mg, Bid	Not Reported
Hydroxychloroquine	C	Oral	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18011688	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055223		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	1000 Milligram 2 Every 1 Day		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Diclofenac	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18011798	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-20_00009837		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haematotoxicity; Haemoglobin Decreased; Hypokalaemia; Intentional Overdose; Muscular Weakness; Nausea; Platelet Count Decreased; Somnolence; Suicide Attempt; Treatment Noncompliance; Ventricular Tachycardia; Vomiting	Methotrexate			S	Oral	Strength: 2.5 Mg		Not Reported
	Prednisone			S	Oral	Strength: 10 Mg		Not Reported
	Hydroxychloroquine			S	Oral	Strength: 200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18011885	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-MAPI_00010561			Unknown	CAN

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

Drug Ineffective; Laboratory Test Abnormal	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Weekly,Dose 12.5-25 Mg,Qwk	Not Reported
	Abatacept	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hyzaar	C			Not Reported
	Effexor	C			Not Reported
	Folic Acid	C			Not Reported
	Enbrel	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18011897	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201702-001092			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Injury; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18011977	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201702-001108			Unknown	CAN

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

Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Decreased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Unevaluable Event; Vision Blurred; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	300 Mg, Qd	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	Unk	Concordia
	Prednisone	S	Unknown	7.5 Mg, Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg Weekly	Not Reported
	Paracetamol	S	Oral	65 Mg, Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Hydromorphone Hydrochloride	S	Unknown	Unk	Not Reported
	Hydromorphone Hydrochloride	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	520 Mg, Q4w	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg	Not Reported
	Humira	C			Not Reported
	Orencia	C			Not Reported
	Remicade	C			Not Reported
	Diphenhydramine Hydrochloride	C			Not Reported
	Fosavance	C			Not Reported
	Hydrocortisone	C			Not Reported
	Hyzaar	C			Not Reported
	Methylprednisolone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18011994	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202006006999			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rash; Renal Impairment	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported

	Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012030	EXPEDITED (15-DAY)		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03177		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk, High Doses		Lupin
	Methylprednisolone			S	Unknown	32 Milligram, Qd		Lupin
	Lopinavir + Ritonavir			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012079	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007048			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Citrate Free		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054682		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	20 Nanogram		Not Reported
	Arava			S	Unknown	10 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram 1 Every 2 Weeks		Not Reported

Hydroxychloroquine	S	Unknown	200 Milligram		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk		Not Reported
Prednisone	S	Unknown	20 Nanogram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2 Gram, 1 Every 6 Months		Not Reported
Sulfasalazine	S	Unknown	500 Milligram 2 Every 1 Days		Not Reported
Sulfasalazine	S	Unknown	1000 Milligram 2 Every 1 Days		Not Reported
Risedronate Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012391	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Rosuvastatin Calcium			S	Unknown			Teva
	Mycophenolic Acid			S	Unknown	2 Dosage Forms Daily;		Teva
	Piperacillin W/Tazobactam			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Ceftazidime			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Plaquenil			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amiodarone Hydrochloride			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Eprex (Epoetin Alfa)			C	Intravenous (not otherwise specified)			Not Reported

	Escitalopram	C	Unknown	Not Reported
	Hydrochloroquine (Medication Unknown)	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Insulin Lispro	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Piperacilina + Tazobactum	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Risedron	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Slow K	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Ventolin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012488	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007042			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache	Hydroxychloroquine			S		Over 5 Years		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012498	EXPEDITED (15-DAY)		OT	CA-ACCORD-189612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Methotrexate			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Hydroxychloroquine	S		Not Reported
	Leflunomide	S		Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012629	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-252899		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Meropenem			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	1 Milligram, Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012632	EXPEDITED (15-DAY)		DE, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-253052		72 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sepsis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisolone			S	Unknown	2.5 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012648	EXPEDITED (15-DAY)		DE, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-253064		66 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intra-Abdominal Haemorrhage	Sulfasalazine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	5 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012682	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012828	EXPEDITED (15-DAY)		DE	NVSC2020PT194451			Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Death; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012877	EXPEDITED (15-DAY)		OT	CA-ACCORD-189557			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012880	EXPEDITED (15-DAY)		OT	CA-ACCORD-189604		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012887	EXPEDITED (15-DAY)		OT	CA-ACCORD-189556			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Arava			C		1 Every 1 Days		Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012888	EXPEDITED (15-DAY)		OT	CA-ACCORD-189530		62 YR	Female	CAN

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

Drug Ineffective; Laboratory Test Abnormal	Methotrexate	S				Accord
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S				Not Reported
	Hydroxychloroquine	S				Not Reported
	Leflunomide	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Days		Not Reported
	Folic Acid	C				Not Reported
	Hyzaar	C				Not Reported
	Venlafaxine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012893	EXPEDITED (15-DAY)		OT	CA-ACCORD-189537		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate			S				Accord
	Arava			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012898	EXPEDITED (15-DAY)		OT	CA-ACCORD-189600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Accord
	Azathioprine/Azathioprine Sodium			S	Unknown	Not Specified		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Naproxen			S	Unknown	Not Specified		Not Reported
	Pms-Azithromycin			S	Unknown	Not Specified		Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012920	EXPEDITED (15-DAY)		OT	CA-ACCORD-189331			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Plaquenil			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012923	EXPEDITED (15-DAY)		OT	CA-ACCORD-189960			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporosis	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012942	EXPEDITED (15-DAY)		OT	CA-ACCORD-189547		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Erythema; Drug Ineffective; Hypoacusis; Product Use Issue; Psoriatic Arthropathy	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Oral	Every 1 Days		Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			C	Oral	Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013306	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054681			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown	2 Milligram, 1 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013423	EXPEDITED (15-DAY)		OT	CA-ACCORD-189561		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

			otherwise specified)	Intravenous		
	Risedronic Acid	S	Unknown	1 Every 1 Weeks, Not Specified		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine	C	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013501	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-032972		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clindamycin			S	Oral	Unk		Aurobindo
	Cyclobenzaprine			S	Oral	Unk		Aurobindo
	Esomeprazole			S	Oral	Unk		Aurobindo
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013607	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798535		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013611	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Rosuvastatin Calcium			S	Unknown	20 Milligram Daily;		Teva
	Ibuprofen			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013727	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798544		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate			S	Unknown			Barr
	Rosuvastatin Calcium			S	Oral	10 Milligram Daily;		Actavis
	Rosuvastatin Calcium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020264741			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Dronabinol			C		Unk		Not Reported
	Cannabis Sativa			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18013893	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018442161		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S		Unk (Therapy Duration: 9 Months)		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Hydroxychloroquine			S	Unknown	200 Milligram,2 Every 1 Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Therapy Duration: 9 Years)		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	426 Mg, Unk	Not Reported
	Remicade	S		Unk (Therapy Duration: 2 Years)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Unknown	40 Milligram, Once Every 2 Weeks/40 Mg, Unk (1 Every 2 Weeks, Therapy Duration: 346 Days)	Not Reported
	Xeljanz	C		5 Milligram, 2 Every 1 Day	Not Reported
	Xeljanz	C		5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014094	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053868		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red	Orencia			S	Unknown			Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown	200 Milligram, Qmo		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qwk		Not Reported
	Infliximab			S	Unknown	200 Milligram, Qwk		Not Reported

Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Rituximab	S	Unknown	420 Milligram, Qmo	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014181	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1063252		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hallucinations, Mixed; Insomnia; Leukocytosis; Mania; Off Label Use	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Methylprednisolone			S	Unknown	32 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014298	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020264739		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Bone Marrow Toxicity; C-Reactive Protein Increased; Neuropathy Peripheral; Paraesthesia; Rash; Thrombocytopenia	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	680 Mg, Weekly		Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown	10 Mg		Not Reported
	Acetaminophen			C	Oral	650 Mg		Not Reported

	Diphenhydramine	C	Oral	50 Mg		Not Reported
	Lyrica	C				Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014321	DIRECT	Y				74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Electrocardiogram Qt Prolonged; Unresponsive To Stimuli; Ventricular Fibrillation	Azithromycin			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Ceftriaxone Sodium			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014378	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1063493		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Venlafaxine			S	Unknown	250 Mg/24h,		Not Reported
	Venlafaxine			S	Unknown	Later, Reinitiated At 150 Mg/24h.		Not Reported
	Lopinavir/Ritonavir			S	Unknown	400mg/100mg Every 12h		Not Reported
	Azithromycin			S	Unknown	250 Mg/24 H		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg/24 H		Mylan
	Vortioxetine			C	Unknown	10 Mg/24h		Mylan
	Vortioxetine			C				Mylan
	Trazodone			C	Unknown	50 Mg/24h		Mylan
	Trazodone			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014389	EXPEDITED (15-DAY)		HO	BE-MYLANLABS-2020M1063580		65 YR	Male	BEL

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

Off Label Use	Azithromycin	S	Unknown	500 Milligram, Qd, On Day 1	Not Reported
	Azithromycin	S	Unknown	250 Milligram, Qd, Scheduled From Day 2-Day 5	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, On Day 1	Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram, On Day 2-Day 5	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014556	NON-EXPEDITED		HO	FR-AMGEN-FRASP2020109562		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia	Amgevita			S	Subcutaneous	40 Milligram, Q2wk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014573	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1798562		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus	Rosuvastatin Calcium			S	Unknown			Teva
	Piperacillin W/Tazobactam			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Ml Daily;		Not Reported
	Plaquenil			S	Unknown	400 Ml Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amiodarone Hydrochloride			C	Unknown			Not Reported

Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Apo-Ketorolac	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Escitalopram	C	Unknown	Not Reported
	Humalog	C	Intravenous (not otherwise specified)	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Slow-K Tablet	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Ventolin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014703	EXPEDITED (15-DAY)		OT	NVSC2020CH190260		76 YR	Male	CHE

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

Acute Generalised Exanthematous Pustulosis; Product Use In Unapproved Indication	Hydroxychloroquine		S	Unknown	400 Mg, Qd (For 4 Weeks)	Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014834	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1798547		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown			Teva
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18015045	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097917			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Arava			S		Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg,Qd		Sanofi
	Enbrel			S	Unknown	50 Mg, 1 Every 1 (Week(S))		Not Reported

Methotrexate	S	Oral	25 Mg,Qd		Not Reported
Myochrysine	S	Intramuscular	25 Mg,Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18015643	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-22087			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18015646	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-22210		45 YR	Female	CAN

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

Alopecia; Drug Ineffective; Drug Specific Antibody; Dry Eye; Feeling Abnormal; Joint Swelling; Metabolic Surgery; Product Use Issue; Sleep Apnoea Syndrome; Vitiligo	Etanercept	S	Other		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Methotrexate	C	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18015850	EXPEDITED (15-DAY)		OT	NVSC2020CN195448		62 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Arbidol			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18016001	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055554			Male	CAN

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

Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia	S	Unknown		Bristol Myers Squibb
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Zostavax	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Diclofenac	C	Unknown	100 Milligram	Not Reported
	Desoximetasone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18016121	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799431			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2000 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18016557	EXPEDITED (15-DAY)		OT	CA-SA-2020SA176996			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Intolerance; Insomnia; Off Label Use; Product Use Issue; Syncope; Therapeutic Response Decreased	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Folic Acid			S		Unk (5 Mg Per Daay, 3 Times A Week)		Not Reported
	Paracetamol			S		Unk		Not Reported
	Vimovo			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18016621	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055765		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	S	Oral		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18017297	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Packaging Confusion	Hydroxychloroquine Sulfate			S				Not Reported
	Hydrochlorothiazide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18017385	EXPEDITED (15-DAY)		OT	NVSC2020ES191882		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Hydroxychloroquine			S	Oral	1 Df, Q12h, 400 Mg C/12 Horas Seguido De 200 Mg C/12 Horas		Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Df, Q12h		Not Reported
	Deprax			C	Unknown	Unk		Not Reported
	Omeprazol			C	Unknown	Unk		Not Reported
	Rhinomer Nasal Spray			C	Unknown	Unk		Not Reported
	Manidon			C	Unknown	Unk		Not Reported
	Sintrom			C	Unknown	Unk		Not Reported

Paracetamol	C	Unknown	Unk		Not Reported
Duphalac	C	Unknown			Not Reported
Bisoprolol	C	Unknown	Unk		Not Reported
Seretide	C	Unknown	Unk		Not Reported
Escitalopram	C	Unknown	Unk		Not Reported
Humalog	C	Unknown	Unk		Not Reported
Fursemida	C	Unknown	Unk		Not Reported
Alprazolam	C	Unknown	Unk		Not Reported
Sinemet Plus	C	Unknown	Unk		Not Reported
Atrovent	C	Unknown	Unk		Not Reported
Noctamid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18017752	EXPEDITED (15-DAY)		DS	CA-ROCHE-2638423			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Liver Disorder; Loss Of Personal Independence In Daily Activities; Oral Herpes	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Orencia			C				Not Reported
	Voltaren [Diclofenac Diethylamine]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18017756	EXPEDITED (15-DAY)		OT	CA-ROCHE-2636890		58 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Intentional Product Use Issue; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Kevzara	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18017972	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-032973		14 YR	Female	USA

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

Completed Suicide	Ibuprofen 200 Mg Tablets Usp (Otc)		S	Oral	200 Milligram	Aurobindo
	Naproxen		S	Oral	750 Milligram	Not Reported
	Hydroxychloroquine		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	11476817	EXPEDITED (15-DAY)		DS, HO, OT	US-JAZZ-2014-US-010624			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Brain Injury; Carbon Monoxide Poisoning; Carpal Tunnel Syndrome; Cyst Removal; Epilepsy; Infusion; Limb Operation; Loss Of Consciousness; Post Procedural Complication; Pruritus; Sciatica; Suicidal Ideation	Xyrem			S	Oral	1.75 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	11909048	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-092211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	12696508	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1477		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Therapeutic Response Decreased; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown	Usual Dose > 3 Months		Not Reported
	Enbrel			S	Unknown	Usual Dose > 3 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Usual Dose > 3 Months		Not Reported
	Apo-Leflunomide			S	Unknown	Usual Dose > 3 Months		Not Reported
	Plaquenil			S	Unknown	Usual Dose > 3 Months		Not Reported
	Humira			S	Subcutaneous	Usual Dose > 3 Months		Not Reported
	Cimzia			S	Transmammary	Usual Dose >3 Month		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Usual Dose >3month		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	13063419	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0803		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Condition Aggravated; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hypersensitivity; Hypertension; Pneumonia; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Estradiol	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Xalatan	C	Unknown	Not Reported
Dorzolamide Hcl/Timolol Maleate	C	Unknown	Not Reported
Baclofen	C	Unknown	Not Reported
Levaquin	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported
Potassium Chloride	C	Unknown	Not Reported
Zingiber Officinale	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Estrogel	C	Unknown	Not Reported
Atasol [Paracetamol]	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	13580102	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Mobility Decreased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	14150758	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2145793-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Dose: 50 Die		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Imuran			C				Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	14198690	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3643		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported

Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	14496013	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007268		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Orencia			S	Unknown	1000 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Erythro Base			S	Unknown	Unk		Not Reported
	Erythromycin			S	Subcutaneous	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported

Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	22.5 Mg, Qwk	Not Reported
Methotrexate	S	Oral	17.5 Milligram, Qwk	Not Reported
Novo-Rythro	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Remicade	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Risedronate	S	Oral	35 Milligram, Qwk	Not Reported
Risedronate	S	Unknown	Unk	Not Reported
Celebrex	C	Unknown	200 Milligram, Bid	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	4000 International Unit, Qd	Not Reported
Cannabis Sativa	C	Unknown	Unk	Not Reported
Marijuana	C	Unknown	Unk	Not Reported
Bupropion	C	Unknown	Unk	Not Reported
Wellbutrin	C	Unknown	300 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15049818	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015756		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15394598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184764		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 274.0 Days		Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Apo-Leflunomide			S	Unknown					Not Reported
	Arthrotec			C	Unknown					Not Reported
	Ergocalciferol			C	Unknown					Not Reported
	Imuran			C	Unknown					Not Reported
	Azathioprine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15578892	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Imuran	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	C	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15620376	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556697-00		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15622705	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557477-00		36 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15689905	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324553AA			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Anakinra			S		50 Mg, Qd		Not Reported
	Humira Ac			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Infliximab			S	Intravenous (not	3 Mg, Qw		Not Reported

				otherwise specified)		
	Methotrexate		S			Not Reported
	Orencia		S	Intravenous (not otherwise specified)	250 Mg	Not Reported
	Prednisone		S	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine		S	Oral	250 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15922154	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2652807-00		75 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15934011	EXPEDITED (15-DAY)		CA, DS, OT	CA-ABBVIE-19K-028-2656831-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Indomethacin			S	Unknown				Not Reported
	Leflunomide			S	Oral				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Oral				Not Reported
	Prednisone			S	Oral				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Cymbalta			C					Not Reported
	Folic Acid			C					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	15941746	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653100-00		52 YR	Female	CAN

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

	Methotrexate		S	Unknown		Not Reported
	Mtx		S	Unknown		Not Reported
	Mtx		S	Unknown	Dose Reduced	Not Reported
	Mtx		S	Unknown	Dose Increased	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16095151	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2710698-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass			C				Not Reported
	Amoxil			C				Not Reported
	Amoxicillin And Clavulanate Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16234392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-036882		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16470169	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016509		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure	Ciprofloxacin			S	Unknown	Unk		Apotex
	Clindamycin			S	Unknown			Not Reported

Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Enalapril	S	Unknown		Apotex
	Hydrochlorothiazide	S	Unknown		Apotex
	Losartan	S	Unknown	Unk	Apotex
	Hydralazine	S	Unknown		Apotex
	Moxifloxacin	S	Unknown	Unk	Apotex
	Pantoprazole	S	Unknown		Apotex
	Penicillin	S	Unknown	Unk	Apotex
	Metoprolol	S	Unknown		Not Reported
	Cefalexine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Celebrex	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Unk	Not Reported
	Pariet	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Avelox	S	Unknown	Unk	Not Reported
	Penicilin G	S	Unknown	Unk	Not Reported
	Penicillin Nos	S	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported

	Cipro /00697201/	C	Unknown			Not Reported
	Venofer	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16499718	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170685			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Pregabalin			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S		Unk Unk, Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qw		Not Reported
	Tylenol [Paracetamol]			C		Unk Unk, Unk		Not Reported
	Paracetamol			C				Not Reported
	Paracetamol			C				Not Reported
	Acetaminophen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16533273	EXPEDITED (15-DAY)		DE, OT	AU-PFIZER INC-2019288524		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Jc Virus Granule Cell Neuronopathy	Methotrexate			S		20 Mg, Weekly		Pfizer
	Methotrexate			S				Pfizer
	Prednisolone			S		12 Mg, Daily		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16836962	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Unknown			Not Reported
Sulfasalazine	S	Oral			Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Vaccinia Immunoglobulins	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16880405	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415332			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16889547	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2953404-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Xeljanz	S	Oral			Not Reported
Tofacitinib	S	Unknown			Not Reported
Cimzia	S	Subcutaneous			Not Reported
Orencia	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous	Form Of Administration: Solution For Injection/Infusion		Not Reported
Adalimumab	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Sarilumab	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Kevzara	S	Unknown			Not Reported
Rabeprazole Sodium	C	Oral			Not Reported
Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	16956996	EXPEDITED (15-DAY)		HO	CA-ROCHE-2438132		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral	Capsule, Hard		Not Reported
	Celebrex			S	Unknown	Capsule, Hard		Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo Celecoxib	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Celecoxib	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Nasonex	C		Not Reported
	Omega-3	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
	Actonel	C		Not Reported
	Ascorbic Acid	C		Not Reported
	Ascorbic Acid	C	Unknown	Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride	C		Not Reported
	Biotin	C		Not Reported
	Calcium	C		Not Reported
	Cholecalciferol	C		Not Reported

	D-Alpha Tocopherol	C	Unknown		Not Reported
	Diphenoxylate	C		1 Dosage Form	Not Reported
	Diphenoxylate Hydrochloride	C			Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Pantoprazole	C			Not Reported
	Pantoprazole	C			Not Reported
	Thiamine Hydrochloride	C			Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17054505	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137954		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Eliquis Film Coated			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17080886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475610		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Cyclical	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17233345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508677		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	10 Mg, 15 Mg		Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Oral	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Pantoprazole Sodium Sesquihydrate	C	Unknown	Not Reported
	Pantoprazole Sodium Sesquihydrate	C	Oral	Not Reported
	Pantoprazole Sodium Sesquihydrate	C	Unknown	Not Reported
	Tenofovir	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17295895	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524847		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Benzylpenicillin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
	Rocuronium Bromide	S	Unknown		Not Reported
	Rocuronium Bromide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Phenoxymethylpenicillin Potassium	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17337625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased;	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Pneumonia; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17364086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537110			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17365665	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025313			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Plaquenil			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Otezla	S	Unknown	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17417741	EXPEDITED (15-DAY)		HO	CA-ROCHE-2547886		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Morphine			C	Topical			Not Reported
	Erythromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17803361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237155		59 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Hand Deformity; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate	S	Unknown		Barr
	Prednisone	S	Unknown		Actavis
	Prednisone	S			Actavis
	Tocilizumab	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Oral	25 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported

	Cortisone Acetate		S	Unknown	Not Reported
	Cortisone Acetate		S		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride		S	Unknown	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Apo-Prednisone		S	Unknown	Not Reported
	Reactine [Cetirizine]		S	Unknown	Not Reported
	Diclofenac		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17815692	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184306			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Mirtazapine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17819012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17844590	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2606292		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Aleve	C		Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Bupropion	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17855313	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020215777		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17858005	EXPEDITED (15-DAY)		HO	CA-ROCHE-2608888		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported

Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported

Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Duration: 365	Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous	Cyclical	Not Reported
Fosamax	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Cyclosporin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17916349	EXPEDITED (15-DAY)		OT	ES-ROCHE-2623278		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Intentional Product Use	Roactemra			S	Intravenous (not otherwise specified)			Not Reported

Issue; Off Label Use	Ceftriaxone	S	Intravenous (not otherwise specified)	Not Reported
	Azitromicina	S	Oral	Not Reported
	Hidroxicloroquina Sulfato	S	Oral	Not Reported
	Enoxaparin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17927964	EXPEDITED (15-DAY)		LT, OT	CA-ROCHE-2624412		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravesical			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone	S	Oral	Not Reported
	Cortisone	S	Oral	Not Reported
	Cortisone	S	Oral	Not Reported
	Cortisone	S	Unknown	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported

Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Golimumab	S	Subcutaneous	Not Reported
Golimumab	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Sunconjunctival	Not Reported
Humira	S	Sunconjunctival	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Kevzara	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Topicort (Canada)	S	Cutaneous	Not Reported
Topicort (Canada)	S	Oral	Not Reported

Topicort (Canada)	S	Oral	Not Reported
Topicort (Canada)	S	Subcutaneous	Not Reported
Topicort (Canada)	S	Cutaneous	Not Reported
Topicort (Canada)	S	Subcutaneous	Not Reported
Topicort (Canada)	S	Unknown	Not Reported
Winpred	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Lisinopril	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Zyrtec-D	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17929899	EXPEDITED (15-DAY)		OT	CA-ACCORD-186283		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17933017	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP015497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fatigue; Insomnia; Joint Swelling; Pain In Extremity; Pruritus; Synovitis	Ibuprofen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17974667	EXPEDITED (15-DAY)		OT	NVSC2020ES173500		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome; Product Use In Unapproved Indication	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported
	Ceftriaxone			S	Unknown	Unk (No Especificada- Not Specified)		Novartis
	Ceftriaxone			S	Unknown	No Especificada		Novartis
	Azitromicina			S	Unknown	Unk (No Especificada- Not Specified)		Not Reported
	Midazolam			S	Unknown	Unk		Not Reported
	Midazolam			S				Not Reported
	Dolquine			S	Oral	A Compressed Breakfast And Dinner		Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Omnic Ocas			C	Unknown	Unk (Prolonged-Release Tablets Coated With Film; 30 Tablets)		Not Reported
	Omnic Ocas			C	Unknown	Unk		Not Reported
	Cortic			C	Unknown	Unk (Corticoides A Dosis Bajas- Low Dose Corticoids)		Not Reported
	Manidon Hta			C	Unknown	Unk (30 Tablets)		Not Reported
	Rilast Turbohaler			C	Respiratory (inhalation)	Unk (160 Mg/ 4.5 Mg; 1 Inhaler Of 120 Doses)		Not Reported
	Simvastatin			C	Unknown	Unk (28 Tablets)		Not Reported
	Kalpress			C	Unknown	Unk (28 Tablets (Al/Pvc/Pe/Pvdc))		Not Reported
	Kalpress			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017087	EXPEDITED (15-DAY)		OT	CA-ACCORD-189592		61 YR	Female	CAN

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

Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate		S	Unknown	1 Every 1 Weeks	Accord
	Hydroxychloroquine		S	Oral	2 Every 1 Days	Not Reported
	Xeljanz		S	Oral	2 Every 1 Days	Not Reported
	Humira		S	Subcutaneous	Subcutaneous Solution	Not Reported
	Folic Acid		S	Unknown	1 Every 1 Weeks	Not Reported
	Cimzia		S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe	Not Reported
	Arava		S	Oral		Not Reported
	Prednisone		S	Unknown		Not Reported
	Leflunomide		S	Oral	1 Every 1 Days	Not Reported
	Actemra		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017199	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-03234		64 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Vancomycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Kaletra			S	Unknown	Unk		Not Reported
	Imipenem			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017202	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-03232		65 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin

	Kaletra	S	Unknown	Unk		Not Reported
	Imipenem	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017209	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-03233		50 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Vancomycin Hydrochloride			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Imipenem			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017236	EXPEDITED (15-DAY)		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03274		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Encephalopathy; Off Label Use; Serotonin Syndrome; Urinary Retention	Duloxetine			S	Unknown	120 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Lopinavir/Ritonavir			S	Unknown	400/100 Mg, Bid		Not Reported
	Lithium			S	Unknown	800 Milligram, Qd		Not Reported
	Haloperidol			S	Unknown	1 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017239	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056010		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoarthritis; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	200 Milligram		Not Reported
Leflunomide	S	Unknown	10 Milligram		Not Reported
Methotrexate	S	Unknown	15 Milligram		Not Reported
Remicade	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Simponi	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017655	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056019		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, 2 Every 1 Day		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, 2 Evevry 1 Day		Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Evevry 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017699	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Celebrex			S	Unknown	20 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown			Not Reported

Rituximab	S	Unknown			Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Bid		Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18017878	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054753			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18018007	EXPEDITED (15-DAY)		CA, DE, OT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-051733			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature	Esomeprazole			S	Transplacental	20 Milligram, Qd		Zydus Pharm
	Diffu K			S	Transplacental	1 Dosage Form, Qd		Not Reported
	Imurel [Azathioprine]			S	Transplacental	150 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Transplacental	400 Milligram, Qd		Not Reported
	Cortancyl			S	Transplacental	5 Milligram, Qd		Not Reported

Separation Of Placenta; Right-To-Left Cardiac Shunt

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18018264	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051081			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Ertapenem			S	Intravenous (not otherwise specified)	1 Gram, Qd		Not Reported
	Piperacilin/Tazobactam			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Dolquine			S	Oral	400 Milligram, Qd		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18018266	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051071			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Propofol			S	Intravenous (not otherwise specified)	6.6 Milligram/Kilogram (Every Hour)		Not Reported
	Dolquine			S	Oral	400 Milligram, Qd		Not Reported
	Dolquine			S				Not Reported
	Dexametasona [Dexamethasone]			C	Intravenous (not otherwise specified)	4 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18018406	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	420 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	420 Milligram, Qd		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Qwk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine		S	Unknown	1 Gram 2 Every 1 Day	Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019325	EXPEDITED (15-DAY)		OT	NVSC2020US196201		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoxia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019329	EXPEDITED (15-DAY)		LT, OT	ES-AUROBINDO-AUR-APL-2020-035008		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Unknown	Unk, 500 Mg / 24 The First Day And Then Low Dose At 250 Mg / 24		Aurobindo
	Lopinavir			S	Unknown	Unk, Two Times A Day (200/50 Every 2 Tablets Every 12 Hours)		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019453	EXPEDITED (15-DAY)		HO	CA-ACCORD-189782		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Gabapentin			S	Oral	2 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not	1 Every 1 Months		Not Reported

Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure			otherwise specified)		
	Celecoxib	S	Oral		Not Reported
	Enbrel	S	Unknown	1 Every 1 Weeks	Not Reported
	Fentanyl	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Myochrysine	S	Intramuscular	1 Every 3 Weeks	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days	Not Reported
	Zoledronic Acid	C	Intravenous (not otherwise specified)		Not Reported
	Diphenoxylate	C			Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	C			Not Reported
	Iron	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Oxycodone	C			Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C			Not Reported
	Risedronic Acid	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019461	EXPEDITED (15-DAY)		HO	CA-ACCORD-189874		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not	Frequency: 1 Every 1		Not Reported

		otherwise specified)	Months	
Apo-Gabapentin	S	Oral	Frequency: 2 Every 1 Days	Not Reported
Celebrex	S	Oral		Not Reported
Enbrel	S		Frequency: 1 Every 1 Weeks	Not Reported
Fentanyl	S			Not Reported
Hydroxychloroquine	S		Frequency: 1 Every 1 Days	Not Reported
Myochrysine	S	Intramuscular	Dosage Firn: Solution Intramuscular, Frequency: 1 Every 3 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Months	Not Reported
Oxycontin	S			Not Reported
Sulfasalazine	S	Oral	Frequency: 1 Every 1 Days	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Months	Not Reported
Diphenoxylate	C		Frequency: 1 Every 1 Days	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C		Frequency: 2 Every 1 Days	Not Reported
Ergocalciferol	C	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Weeks	Not Reported
Esomeprazole	C		Frequency: 2 Every 1 Days	Not Reported
Iron	C		Frequency: 1 Every 1 Days	Not Reported
Loperamide	C			Not Reported
Nasonex	C		Dosage Form: Spray, Metered Dose, Frequency: 2 Every 1 Days	Not Reported
Oxycodone	C			Not Reported
Pantoprazole	C		Frequency: 1 Every 1	Not Reported

				Days	
	Prednisone	C		Frequency: 1 Every 1 Days	Not Reported
	Risedronic Acid	C		Frequency: 1 Every 1 Weeks	Not Reported
	Trazodone	C	Oral	Frequency: 1 Every 1 Days	Not Reported
	Tylenol	C	Oral	Frequency: 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056162		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019540	EXPEDITED (15-DAY)		OT	CA-ACCORD-189524		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease	Methotrexate			S				Accord
	Anakinra			S				Not Reported
	Apo-Warfarin			S				Not Reported
	Celebrex			S				Not Reported

Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S			Not Reported
	Sulfasalazine	S			Not Reported
	Warfarin	S			Not Reported
	Enbrel	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019605	EXPEDITED (15-DAY)		OT	CA-ACCORD-190122		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Certolizumab			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Not Specified		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019610	EXPEDITED (15-DAY)		OT	CA-ACCORD-190149		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Accord
	Lyrica			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Metformin			S	Unknown	2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Acetaminophen			C	Unknown			Not Reported

Altace	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Tocopherol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Rosuvastatin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019633	EXPEDITED (15-DAY)		DE, OT	CA-ACCORD-189172		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Methotrexate			S		1 Every 1 Weeks		Accord
	Sulfasalazine			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Rituximab			S				Not Reported
	Remicade			S				Not Reported
	Orencia			S				Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S				Not Reported
	Etanercept			S		1 Every 1 Weeks		Not Reported
	Doxycycline			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C				Not Reported
	Rituximab			C				Not Reported
	Simponi			C				Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Remicade			S				Not Reported

	Humira	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019640	EXPEDITED (15-DAY)		OT	CA-ACCORD-189443			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Product Use Issue; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Depo-Medrol With Lidocaine			S	Intra-articular			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Ketoprofen			S	Topical	Not Specified		Not Reported
	Folinic Acid			S	Unknown			Not Reported
	Prevnar 13			S	Intramuscular			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019648	EXPEDITED (15-DAY)		OT	CA-ACCORD-190158		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper;	Hydrochlorothiazide			S	Unknown			Not Reported

Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Pantoprazole	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Avelox	S	Unknown		Not Reported
	Biaxin	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	S	Unknown		Not Reported
	Cephalexin	S	Unknown		Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Clindamycin	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enalapril	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydralazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Levaquin	S	Unknown		Not Reported
	Losartan	S	Unknown		Not Reported
	Metoprolol	S	Unknown		Not Reported
	Moxifloxacin/Moxifloxacin Hydrochloride	S	Unknown		Not Reported
	Pariet	S	Unknown	Tablet (Enteric- Coated)	Not Reported
	Benzylpenicillin	S	Unknown		Not Reported
	Penicillin Nos	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	C	Unknown		Not Reported
	Cipro	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

Prednisone	C	Unknown		Not Reported
Veltassa	C			Not Reported
Venofer	C	Unknown		Not Reported
Biaxin	S			Not Reported
Cephalexin	S	Unknown		Not Reported
Ciprofloxacin	S	Unknown		Not Reported
Hydrochlorothiazide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019675	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202006007144			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Condition Aggravated; Eosinophil Count Decreased; Haematocrit Decreased; Neutrophil Count Decreased; Red Blood Cell Count Decreased; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019690	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056101		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate	Orencia			S	Subcutaneous	750 Milligram		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Abnormal; Synovitis	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020148	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2952092-00		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Synthroid			C				Not Reported
	Naproxen			C		3 Times In A Day As Needed		Not Reported
	Tramadol			C		As Needed		Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020250	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799196			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Systemic Lupus Erythematosus	Arava	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020251	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799327			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020253	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799264		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020254	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799303		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Increased; Blood Pressure Systolic Increased; Drug Ineffective; Heart Rate Decreased; Infusion Related Reaction; Nasopharyngitis; Stomatitis; White Blood Cell Count Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020257	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799334		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020258	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799335			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020285	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1799417		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion;	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown	50 Milligram Daily;		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram Daily;		Not Reported

Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
	Prednisone	S	Oral	6 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020287	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2020-CA-1799433		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bacteraemia; Body Temperature Increased; Central Nervous System Infection; Clostridium Difficile Infection; Confusional State; Decreased Appetite; Depressed Level Of Consciousness; Diarrhoea; Escherichia Infection; Headache; Nausea; Nervous System Disorder; Seizure; Somnolence; Stress Ulcer; Strongyloidiasis; Thrombosis; Upper Gastrointestinal Haemorrhage; Vomiting; Weight Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799362		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020394	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1064125		68 YR	Male	PRT

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

Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Off Label Use	Lopinavir/Ritonavir	S	Oral	2 Dosage Form, Qd,1 Cp 12/12h	Not Reported
	Plaquinol	S	Oral	400mg 12/12h Em D0 E Depois 200mg 12/12h	Mylan
	Acetylsalicylic Acid	C	Oral	100 Milligram, Qd,Apos Refeica	Mylan
	Omeprazole	C	Oral	20 Milligram, Qd	Mylan
	Nolotil /06276702/	C		2000 Milligram, Prn	Mylan
	Bisoprolol	C	Oral	5 Milligram, Qd	Mylan
	Paracetamol	C	Oral	1000 Milligram, Prn	Mylan
	Paracetamol	C	Intravenous (not otherwise specified)	1000 Milligram, Prn	Mylan
	Clopidogrel	C	Oral	75 Milligram, Qd	Mylan
	Insulin Human	C		Unk	Mylan
	Bromazepam	C	Oral	1.5 Milligram, Qd	Mylan
	Valsartan	C	Oral	80 Milligram, Qd	Mylan
	Enoxaparin Sodium	C		40 Milligram, Qd	Mylan
	Esomeprazole	C	Oral	20 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020399	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1064128		71 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Covid-19 Treatment; Gamma-Glutamyltransferase Increased; Off Label Use	Lopinavir/Ritonavir			S	Oral	2 Cp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 12/12h Em D0		Mylan
	Omeprazole			C	Oral	20 Milligram, Qd		Mylan
	Paracetamol			C	Oral	As Necessary		Mylan
	Tamsulosin			C	Oral	0.4 Milligram, Qd		Mylan
	Paracetamol			C	Intravenous (not otherwise specified)	1000 Milligram, Prn		Mylan
	Diazepam			C	Oral	5 Milligram, Prn		Mylan

Bromazepam	C	Oral	1.5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020449	EXPEDITED (15-DAY)		HO	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-032		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Calciphylaxis	Calcitriol			S	Unknown			Westward
	Prednisone			S	Unknown			Westward
	Febuxostat			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Oxycodone/Acetaminophen			S	Unknown	10/325mg		Not Reported
	Ferric Citrate			S	Unknown			Not Reported
	Pentoxifylline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Insulin Glargine			S	Unknown			Not Reported
	Sodium Thiosulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020712	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056217		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020782	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799215		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020839	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020851	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056116			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020862	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799258		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Pain; Pruritus; Rash; Swelling	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020863	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799237		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020866	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799274		41 YR	Female	CAN

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

Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Prednisone	S	Unknown	Actavis
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020869	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799245			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020870	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Alendronate Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020871	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020876	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799301		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020879	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799270		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Prednisone			S	Unknown	2.5 Milligram Daily;		Actavis
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Subcutaneous		Not Reported
	Enbrel	C			Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Oral	5 Milligram Daily;	Not Reported
	Humira	C	Subcutaneous		Not Reported
	Indapamide	C	Oral	1.25 Milligram Daily;	Not Reported
	Naproxen	C	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Pantoloc[Pantoprazole]	C	Oral	40 Milligram Daily;	Not Reported
	Perindopril	C	Oral	2 Milligram Daily;	Not Reported
	Tylenol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020880	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799283			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020916	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799364		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Prednisone Acetate			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	200 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020926	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020927	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799344			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Yringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020930	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799323			Female	CAN

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

Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone		S	Unknown	Actavis
	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Cetirizine		S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020932	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799277		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Prednisone			S	Unknown			Actavis
	Tocilizumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021156	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1799747		90 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva
	Quetiapine			S	Oral	50 Mg		Teva
	Darunavir			S	Oral	800 Mg		Teva
	Cobicistat			S	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021206	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799372		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Acetaminophen			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported

	Cortisone [Hydrocortisone]	C	Not Reported
	Dexamethasone	C	Not Reported
	Gabapentin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021208	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799266			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021211	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799250			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021213	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021311	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2020US196640		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Cough; Covid-19; Dyspnoea Exertional; Hypoxia; Product Use In Unapproved Indication; Pyrexia; Septic Shock	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Norepinephrine			S	Unknown	Unk		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021333	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021382	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799211		58 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021383	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799206			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)			
	Prednisone	S	Oral	3 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021386	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799188		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021387	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Erythematosus	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine [Cetirizine]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021388	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Intracavernous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021447	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021451	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799345			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia;	Prednisone			S	Unknown			Actavis

Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate	S	Unknown	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799368		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	9 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		S	Oral	5 Milligram Daily;	Not Reported
	Acetaminophen		C			Not Reported
	Desoximetasone		C			Not Reported
	Dexamethasone		C			Not Reported
	Gabapentin		C			Not Reported
	Reactine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021808	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799202			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021858	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021897	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020267463		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	Iv Bolus Of 125 Mg Followed Of 60 Mg Every 24 Hours		Pfizer
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day (500 Mg Every 24 Hours)		Pfizer
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, 1x/Day (2 G Every 24 Hours)		Not Reported
	Dolquine			S	Oral	200 Mg, 2x/Day (200 Mg		Not Reported

				Every 12 Hours)	
	Lopinavir/Ritonavir	S	Oral	1 Df, 2x/Day (1 Tablet Every 12 Hours)	Not Reported
	Pulmicort	C	Respiratory (inhalation)	Unk	Not Reported
	Bisoprolol	C		Unk	Not Reported
	Adiro	C			Not Reported
	Deprax [Trazodone Hydrochloride]	C		Unk	Not Reported
	Nolotil [Metamizole Magnesium]	C		Unk	Not Reported
	Enalapril	C		Unk	Not Reported
	Omeprazol	C		Unk	Not Reported
	Potasion	C			Not Reported
	Inhixa	C		Unk	Not Reported
	Paracetamol	C			Not Reported
	Fluimucil	C			Not Reported
	Atorvastatin	C		Unk	Not Reported
	Clopidogrel	C		Unk	Not Reported
	Atrovent	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022131	NON-EXPEDITED			US-TEVA-2020-US-1799937		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Oseltamivir			S	Unknown			Teva
	Oseltamivir			S				Teva
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022147	EXPEDITED (15-DAY)		DE	PT-MYLANLABS-2020M1064136		81 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Diarrhoea; Off Label Use; Renal Failure	Lopinavir/Ritonavir			S	Oral	4 Dosage Form, Qd(2 Comp 12/12h)		Not Reported
	Plaquinol			S	Oral	400 Milligram, Qd(400mg 12/12h Em D0)		Mylan
	Buscopan			C	Oral	30 Milligram, Qd		Mylan
	Furosemide			C	Intravenous (not otherwise specified)	Unk		Mylan
	Paracetamol			C	Intravenous (not otherwise specified)	1000 Milligram, Prn		Mylan
	Enoxaparin Sodium			C		40 Milligram, Qd		Mylan
	Amoxicillin W/Clavulanic Acid			C	Intravenous (not otherwise specified)	3 Dosage Form, Qd		Mylan
	Sodium Chloride			C	Intravenous (not otherwise specified)	Unk		Mylan
	Losartan Potassium/Hydrochlorothiazide			C	Oral	1 Dosage Form, Qd		Mylan
	Salbutamol			C	Respiratory (inhalation)	8 Dosage Form, Qd		Mylan
	Epsicaprom			C	Oral	3000 Milligram, Qd		Mylan
	Clarithromycin			C	Intravenous (not otherwise specified)	1000 Milligram, Qd		Mylan
	Ipratropium Bromide			C	Respiratory (inhalation)	8 Dosage Form, Qd		Mylan
	Piperacillin/Tazobactam			C		3 Dosage Form, Qd		Mylan
	Omeprazole			C	Oral	20 Milligram, Qd		Mylan
	Irbesartan			C	Oral	150 Milligram, Qd		Mylan
	Acetylsalicylic Acid			C	Oral	100 Milligram, Qd		Mylan
	Captopril			C	Oral	25 Milligram, Prn		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022180	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268427			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg,Qd		Not Reported
	Sulfasalazine			S	Oral	1 G,Qd		Not Reported
	Arabloc			S	Unknown			Sanofi
	Apo-Leflunomide			S		20 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022185	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098052			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Qd		Sanofi
	Pregabalin			S	Oral	150 Mg,Bid		Not Reported
	Methotrexate			S	Oral	20 Mg,Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022299	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-22463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			C	Unknown	Unknown		Not Reported
	Glyburide			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Metformin			C	Oral	Unknown		Not Reported
	Mycophenolate Mofetil			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022386	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022547	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1799316		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat Irritation	Azitromicina (7019a)			S		1000 Milligram Daily; 1000 Mg / 1 Day And 500 Mg Rest		Not Reported
	Claritromicina (967a)			S		50 Mg		Not Reported
	Kaletra			S		800 Mg		Not Reported
	Dolquine			S		400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022932	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055866		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Spinal Column Injury; Surgical Failure; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18023045	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055915		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Thyroid Neoplasm	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18023110	EXPEDITED (15-DAY)		DE, LT	ES-MYLANLABS-2020M1062651		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Off Label Use; Tachycardia	Azithromycin			S		(500 Mg/ Dia)		Not Reported
	Digoxina			S		(0.5 Mg/Iv)		Mylan
	Kaletra			S		Unk (532 Mg/133.2 Mg/Dia)		Mylan
	Dolquine			S		Unk (800 Mg Un Dia, 400 Mg 4 Dias)		Mylan
	Levofloxacin			S		(500 Mg/Dia Iv)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18023111	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1062600		71 YR	Male	ESP

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

Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Off Label Use; Throat Irritation	Clarithromycin	S	50 Milligram, Qd		Not Reported
	Azithromycin	S	1000 Mg/ 1 Dia Y 500 Mg Resto		Not Reported
	Kaletra	S	800 Milligram, Qd		Mylan
	Dolquine	S	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18023135	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1062654		90 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Darunavir			S	Oral	800 Milligram, Qd		Not Reported
	Quetiapine			S	Oral	50 Milligram, Qd		Not Reported
	Cobicistat			S	Oral	150 Milligram, Qd		Mylan
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024331	EXPEDITED (15-DAY)		OT	CA-ROCHE-2637362			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Mobicox			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024572	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-019802			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Eye Movement Disorder; Mobility Decreased; Scleroderma	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisone			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	12769954	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076679			Female	CAN

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

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Infliximab	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Rituxan	S	Subcutaneous	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Arava	C	Oral	Unk		Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	13519381	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038159		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Vomiting	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported

Celebrex	S	Unknown	200 Milligram		Not Reported
Naprosyn [Naproxen Sodium]	S	Unknown	500 Mg, Bid		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Apo-Prednisone	S	Unknown	5 Milligram		Not Reported
Arava	S	Oral	Unk		Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Desoximetasone	S	Oral	Unk		Not Reported
Folic Acid	S	Unknown	500 Milligram		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Cortisone Acetate	S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	13852964	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070668		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation;	Orencia			S	Unknown	Unk Unk, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	25 Milligram, Qwk		Not Reported

Osteoporosis; Pain; Rash; Synovitis	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Unk	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Arava	C	Oral	20 Milligram, Qd	Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
	Naproxen	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	14147488	EXPEDITED (15-DAY)		HO	CA-ROCHE-2013417		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Meningitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Oral	For 6 Month		Not Reported
	Orencia			S	Unknown			Not Reported

	Gold	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	15438204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown	Dosage Form: Not Specified	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown	Tablet Extended Release	Not Reported
	Bupropion	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	15623808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555897-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported
	Clavulin	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Bcg	C	Intravesical	Not Reported
	Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Not Reported
	Risedronate	C	Oral	Not Reported
	Amoxicillin And Clavulanate Potassium	C	Unknown	Not Reported
	Adalimumab	C		Not Reported
	Hydroxychloroquine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	15675678	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573363-00		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Xeljanz	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	15990259	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2672998-00		51 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	16211049	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2017SA020214			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Red	Hydroxychloroquine Sulfate			S	Oral	5 Mg		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg/Kg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg		Sanofi
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	70 Mg		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2,Qow		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Oral	5 Mg,Bid		Not Reported
	Prednisone			S	Oral	3 Mg,Bid		Not Reported
	Prednisone			S	Unknown	1.3 Mg, Bid		Not Reported
	Isoniazid/Rifampicin			S	Intravenous (not otherwise specified)	Unk		Sanofi
	Sulfasalazine			S	Oral	250 Mg,Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Naproxen Sodium			S	Unknown			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)	250 Mg,Qm		Not Reported

Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Actemra	S	Intravenous (not otherwise specified)	280 Mg,Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
	Etanercept	S	Subcutaneous	25 Mg,Qw	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg,Qw	Not Reported
	Tocilizumab	S		250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qcy (Every 2 Weel)	Not Reported
	Adalimumab	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg,Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Mg,Qw	Not Reported
	Enbrel	S		12.5 Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg,Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg,Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg,Unk	Not Reported
	Triamcinolone	S	Unknown	Unk Unk,Unk	Not Reported
	Triamcinolone	S	Other	Unk Unk,Unk	Not Reported
	Folic Acid	C			Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	16490546	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1971		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	0.65 Ml Weekly (Injectable) (Reduced To 0.65 Ml Since Start On Xeljanz		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	16687986	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA217094			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		1 Df, Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	16882113	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05704		51 YR	Female	CAN

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

Methotrexate	S	Subcutaneous	Unknown		Not Reported
Methotrexate	S	Oral	Unknown		Not Reported
Methotrexate	S	Parenteral	Unknown		Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Methotrexate	S	Parenteral	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unknown		Not Reported
Methotrexate	S	Other	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Actemra	S	Unknown	Unknown		Not Reported
Actemra	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Solution Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported
Xeljanz	S	Unknown	Unknown		Not Reported
Xeljanz	S	Oral			Not Reported
Tofacitinib	C	Unknown	Unknown		Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	16992316	EXPEDITED (15-DAY)		HO	JP-ADVANZ PHARMA-201910001407			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17305606	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013867			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Allopurinol			C	Unknown	200 Mg, Qd		Not Reported
	Prednisone			C		5 Mg, Bid		Not Reported
	Prednisone			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17448019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555252		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17467057	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008069		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Milligram		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo Ibuprofen			S	Oral	600 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apremilast			S	Oral	30 Milligram, Bid		Not Reported
	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported
	Apremilast			S				Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cyclosporin			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported

Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ibuprofen	S	Oral	600 Milligram, Every 1 Days	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Leflunomide	S	Oral	20 Unk	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Oral	Unk, Qwk	Not Reported
	Methotrexate	S	Oral	Unk, Qwk	Not Reported
	Motrin Children	S	Oral	600 Milligram	Not Reported
	Motrin Children	S	Unknown	6 Dosage Form, Qd	Not Reported
	Motrin Children	S	Oral	600 Milligram, Qd	Not Reported
	Motrin Children	S	Oral	Unk Milligram, Qd	Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S			Not Reported
	Otezla	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported

Etanercept	S	Unknown	Unk	Not Reported
Etanercept	S			Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S			Not Reported
Apo-Cyclosporine	S	Unknown	Unk	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	0.6 Milligram	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	Unk, Qwk	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported

Vitamin D3	C	Oral	200 International Unit		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Oral	35 Milligram, Qwk		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram		Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram		Not Reported
Methotrexate	S	Subcutaneous	10 Milligram		Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
Cannabis Sativa	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17558716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Usp		Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Azathioprine	C		Not Reported
	Ciclosporin	C		Not Reported
	Minocycline	C		Not Reported
	Penicillamine	C		Not Reported
	Prednisone	C		Not Reported
	Actemra	C	Unknown	Not Reported
	Phenylbutazone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17636247	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000018			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Contraindicated Product Administered; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Panacea Biotec
	Hydroxychloroquine			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Metamizole Sodium			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Torasemide			S	Transplacental			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Xarelto			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Dalteparin Sodium			S	Unknown			Not Reported

	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Novaminsulfon	S	Transplacental	Not Reported
	Novaminsulfon	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Rituximab	S	Transplacental	Not Reported
	Enoxaparin Sodium	S	Transplacental	Not Reported
	Misoprostol	C	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Enoxaparin Sodium	C	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Mifegyne	C	Transplacental	Not Reported
	Cyclophosphamide	C	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17710023	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP010277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Ineffective; Drug Intolerance; Eye Disorder; Joint Swelling; Mobility Decreased; Musculoskeletal Pain; Ocular Toxicity; Off Label Use; Pain In Extremity;	Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex
	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	400.0 Mg, Qd		Apotex
	Diclofenac			S	Unknown	50 Mg, Bid		Apotex
	Naproxen			S	Unknown	500 Mg, Q.6h		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Mg, Q.Wk.		Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Surgery; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	40.0 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Oral	20.0 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	15 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	125.0 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Indocid /00003801/	S	Unknown	50 Mg, Tid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17765811	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Off Label Use; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Azathioprine Sodium	C	Not Reported
Cimzia	C	Not Reported
Enbrel	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17804850	EXPEDITED (15-DAY)		HO	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-037471		89 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction	Apixaban			S	Oral	2.5 Milligram, Bid		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17820530	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599273		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C		Not Reported
	Ativan	C		Not Reported
	Ativan	C		Not Reported
	Benadryl Cold	C		Not Reported
	Codeine	C		Not Reported
	Darifenacin	C		Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Intra-articular	Not Reported
	Desoximetasone	C	Intramuscular	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dilaudid	C		Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Dyclonine Hydrochloride	C		Not Reported
	Dyclonine Hydrochloride	C	Unknown	Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C		Not Reported
	Kenalog	C	Intra-articular	Not Reported
	Loperamide	C	Unknown	Not Reported
	Morphine Sulphate	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Plantago Ovata	C		Not Reported
	Restasis	C		Not Reported
	Synthroid	C		Not Reported

	Trimethoprim	C		Not Reported
	Urispas	C		Not Reported
	Vagifem	C		Not Reported
	Rituximab	C	Unknown	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	C		Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17874733	EXPEDITED (15-DAY)		OT	NVSC2020US158999		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Thrombosis	Hydroxychloroquine			S	Unknown	400 Mg, Loading Dose For 2 Doses		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Prednisone			S	Oral	80 Mg, Bid		Not Reported
	Betamethasone			S	Intramuscular	12 Mg, Qd For 2 Doses		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17925240	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021481		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported

	Arava	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	50 Mg, Bid	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Meloxicam	C	Oral	7.5 Mg, Unk	Not Reported
	Meloxicam	C	Oral	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17975064	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020252094		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Drug Effective For Unapproved Indication; Hyperglycaemia; Off Label Use; Product Use In Unapproved Indication	Methylprednisolone Sodium Succinate			S		Unk (High Doses)		Pfizer
	Methylprednisolone Sodium Succinate			S		32 Mg, Daily (During 4 More Days)		Pfizer
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18003394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054655			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18009612	EXPEDITED (15-DAY)		HO, OT	IT-SA-2020SA175975			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Conduction Disorder; Drug Effective For Unapproved Indication; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Azithromycin			S		Unk		Not Reported
	Azithromycin			S				Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	200 Mg, 1x		Sanofi
	Sarilumab			S		200 Mg, 1x		Sanofi
	Perindopril			C				Not Reported
	Emtricitabine;Rilpivirine;Tenofovir Alafenamide			C		Unk, Single Tablet Regimen		Not Reported

	Low Molecular Weight Heparin	C	Prophylactic Dose	Not Reported
	Oxygen	C	Unk	Not Reported
	Cobicistat;Darunavir;Emtricitabine;Tenofovir	C	Single Tablet Regimen	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18021620	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-253017		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperglycaemia; Off Label Use; Psychotic Disorder	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methylprednisolone			S	Unknown	Unk (High Doses)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18021621	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-253003		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Venlafaxine			S	Unknown	225 Mg/24 H For More Than 5 Years		Sun
	Venlafaxine			S	Unknown	150 Milligram, Daily		Sun
	Lopinavir/Ritonavir			S	Unknown	400/100 Mg/12 H		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Ipca
	Azithromycin			S	Unknown	250 Milligram, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18022551	EXPEDITED (15-DAY)		OT	CA-ACCORD-189506		50 YR	Female	CAN

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

Cough; Drug Ineffective; Headache; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Orencia	S	Unknown		Not Reported
	Actemra	S	Unknown	Not Specified	Not Reported
	Celebrex	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	Not Specified	Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Methotrexate	S	Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18022597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032952		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Actemra			S	Unknown	Therapy Details: 1825.0 Days		Not Reported
	Rituximab			S	Unknown	Therapy Duration: 2 Months		Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Frequency: Every 1 Day; Therapy Duration: 2 Years		Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 790 Nos		Not Reported
	Orencia			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Remicade			S	Unknown	Therapy Duration: 8 Months Cyclical		Not Reported
	Anakinra			S	Unknown			Not Reported

Apo-Leflunomide	S	Oral	Therapy Duration 2 Years		Not Reported
Apo-Leflunomide	S	Unknown	Therapy Duration : 730 Days		Not Reported
Arava	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate	S	Unknown	Therapy Duration :790		Not Reported
Plaquenil	S	Unknown			Not Reported
Wellbutrin	C				Not Reported
Sulfasalazine	C				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18022689	EXPEDITED (15-DAY)		LT, OT	BE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-250027		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemolysis; Off Label Use; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Day 1)		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Day 2-5)		Sun
	Azithromycin			C	Unknown	500 Milligram, Daily (Day 1)		Not Reported
	Azithromycin			C	Unknown	500 Milligram, Daily (Day 2-5)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18022861	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-034488		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023062	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2020-034572		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Disorder; Ear Pain; Off Label Use; Otorrhoea	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023094	EXPEDITED (15-DAY)		OT	CA-ROCHE-2636792		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023279	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Dosage Form: Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown	Dosage Form: Not Specified		Not Reported
	Xeljanz			C	Oral			Not Reported

Rheumatoid Arthritis;
Rheumatoid Lung;
Synovial Cyst; Synovitis;
Tenosynovitis; Viral Upper
Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023359	EXPEDITED (15-DAY)		OT	PT-ADVANZ PHARMA-E2B_00010132			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Haemophagocytic Lymphohistiocytosis; Herpes Zoster; Listeria Sepsis; Lymphopenia; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Azathioprine			S	Unknown	Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S				Not Reported
	Cellcept			S	Oral	15 Mg, Weekly		Not Reported
	Cellcept			S	Oral	Unk		Not Reported
	Cellcept			S				Not Reported
	Thalidomide			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023519	EXPEDITED (15-DAY)		DE	CA-ACCORD-190111		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Methotrexate			S				Accord
	Mycophenolic Acid			S				Accord
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S		Frequency: 1 Every 1 Days		Not Reported
	Prednisone			S		Frequency: 1 Every 1		Not Reported

						Days				
	Rituximab			S						Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023550	EXPEDITED (15-DAY)		DE, HO, LT, OT	MX-ADVANZ PHARMA-202007006994			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Covid-19 Pneumonia; Cushing'S Syndrome; Dyspnoea; Gastritis; Haemorrhoids; Influenza; Pyrexia; Rhinorrhoea	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Oral	10 Mg, Weekly		Not Reported
	Deflazacort			S	Oral	6 Mg, Qd		Not Reported
	Tofacitinib Citrate			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Etoricoxib			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D Nos			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Carboxymethylcellulose			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023695	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18023794	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Actemra			S	Subcutaneous	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Form Of Admin: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Dosage Form: Not Specified		Not Reported
	Sulfasalazine			C	Oral	Dosage Form : Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024024	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Dosage Form: Not Specified	Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Other	Dosage Form: Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	Dosage Form: Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024036	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054726		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Vomiting	Orencia			S	Subcutaneous	150 Gram, Therapy Duration: 8 Months		Bristol Myers Squibb
	Celebrex			S	Oral	200 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, For 4 Months		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 4 Years		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Naproxen			S	Unknown	500 Milligram, Bid		Not Reported
	Naproxen			S	Unknown	50 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qwk For 8 Months		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qwk		Not Reported

	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024191	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral	Dosage Form: Not Specified		Boehringer Ingelheim
	Actemra			S	Subcutaneous	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form:Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Dosage Form: Not Specified		Not Reported
	Methotrexate			S	Oral	Dosage Form: Not Specified		Not Reported
	Sulfasalazine			C	Oral	Dosage Form: Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024259	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density	Mobicox			S	Unknown			Boehringer Ingelheim

Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Actemra	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular	Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown	Dosage Form: Not Specifed	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024876	EXPEDITED (15-DAY)		OT	NVSC2020SA196895		30 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Product Use In Unapproved Indication; Systemic Lupus Erythematosus	Esomeprazole			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Mg		Not Reported
	Prednisolone			S	Unknown	10 Mg		Novartis
	Prednisolone			S	Unknown	40 Mg		Novartis
	Prednisolone			S	Oral	60 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported

	Vancomycin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024924	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20200707023		90 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Darunavir			S	Oral			Janssen
	Cobicistat			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024962	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-034336			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Interval; Hypothermia; Off Label Use; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Not Reported
	Propofol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024990	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-034491		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025241	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020268182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Psoriasis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Cosentyx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025303	EXPEDITED (15-DAY)		DS	CA-ACCORD-190397			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025304	EXPEDITED (15-DAY)		OT	CA-ACCORD-190398			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025305	EXPEDITED (15-DAY)		OT	CA-ACCORD-190400		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Leflunomide			S	Oral	1 Every 24 Hours		Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Folic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025306	EXPEDITED (15-DAY)		OT	CA-ACCORD-190401			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025309	EXPEDITED (15-DAY)		OT	CA-ACCORD-190405			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Embrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025323	EXPEDITED (15-DAY)		OT	CA-ACCORD-190406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025688	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056470		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

	Naproxen	C	Unknown	Unk	Not Reported
	Tylenol With Codeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056511			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025861	EXPEDITED (15-DAY)		DE, LT	ES-TEVA-2020-ES-1799298		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Azitromicina (7019a)			S		500 Mg / Day		Not Reported
	Kaletra			S		532 Mg / 133.2 Mg / Day		Not Reported
	Levofloxacino (2791a)			S	Intravenous (not otherwise specified)	500 Mg / Day Iv		Not Reported
	Digoxina (770a)			S	Intravenous (not otherwise specified)	0.5 Mg/Iv		Not Reported
	Dolquine			S		800 Mg One Day, 400 Mg 4 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18025919	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18026093	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799444		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18026136	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020232507		77 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Deep Vein Thrombosis	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G		Not Reported
	Enoxaparin			S	Subcutaneous	80 Mg		Not Reported
	Ritonavir			S	Oral	50 Mg		Not Reported
	Anakinra			S	Intravenous drip	100 Mg, Every 6 Hours		Not Reported
	Lopinavir			S	Oral	200 Mg		Not Reported
	Hydrochlorothiazide			C	Oral	12.5 Mg		Not Reported
	Pentoxifylline			C	Oral	600 Mg, 1x/Day		Not Reported
	Atorvastatin			C	Oral	80 Mg		Not Reported
	Atorvastatin			C	Oral	70 Mg		Not Reported
	Clopidogrel			C	Oral	75 Mg		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Omeprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Carvedilol			C	Oral	25 Mg		Not Reported
	Iron			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetylcysteine			C	Intravenous (not otherwise specified)	1200 Mg		Not Reported
	Piperacillin/Tazobactam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg		Not Reported

Amlodipine	C	Oral	10 Mg, 1x/Day		Not Reported
Valsartan	C	Oral	160 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18026197	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056467		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18026274	EXPEDITED (15-DAY)		OT	AU-INCYTE CORPORATION-2020IN006535			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Eye Movement Disorder; Mobility Decreased; Scleroderma; Therapeutic Product Effect Incomplete	Jakavi			S	Unknown	10 Mg, Bid		Incyte
	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg		Not Reported
	Prednisone			S	Unknown	Up To 50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	0.25 Mg/Kg		Not Reported

	Prednisolone		S	Unknown	1 Mg/Kg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18026448	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1050819		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia; Off Label Use	Azithromycin			S	Unknown	Not Specified		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Every 12 Hours Followed By 200 Mg Every 12 Hours		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Ceftriaxona /00672201/			S	Unknown	Not Specified		Mylan
	Lopinavir And Ritonavir 200mg/50mg Tablets			S	Oral	400 Mg Every 12 Hours		Mylan
	Lopinavir And Ritonavir 200mg/50mg Tablets			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027206	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX014008		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Unknown		Baxter
	Acetazolamide			S	Unknown	Dosage Form: Not Specified		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Amlodipine			S	Unknown	Dosage From: Tablets		Not Reported
	Azathioprine			S	Unknown	Dosage Form: Not Specified		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Dosage Form: Not Specified		Not Reported

Ciclosporin	S			Not Reported
Enalapril	S	Unknown	Dosage Form: Unknown	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown		Not Reported
Ferrous Fumarate	S	Unknown	Dosage Form: Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Dosage Form: Unknown	Not Reported
Insulin	S	Unknown	Dosage Form: Unknown	Not Reported
Leflunomide	S	Unknown	Dosage Form: Tablets	Not Reported
Leflunomide	S			Not Reported
Metformin	S	Unknown	Dosage Form: Tablets	Not Reported
Methotrexate	S	Unknown	Dosage Form: Unknown	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Nutropin	S	Subcutaneous	Dosage Form: Liquid	Not Reported
Prednisone	S	Unknown	Dosage Form: Unknown	Not Reported
Protropin	S	Intramuscular	Dosage Form: Liquid	Not Reported
Ranitidine	S	Unknown	Dosage Form: Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Dosage Form: Unknown	Not Reported
Testosterone	S	Unknown	Dosage Form: Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
Remicade	S			Not Reported
Remicade	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027335	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799648		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache;	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Etanercept			S	Unknown			Not Reported

Herpes Zoster; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Therapeutic Product Effect Decreased; Ulcer	Humira	S	Unknown	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Unknown	5 Milligram Daily;	Not Reported
	Betaloc [Metoprolol Tartrate]	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Losec [Omeprazole]	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027362	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027409	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799856		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Nanogram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Nanogram Daily;		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027703	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1799430		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell	Prednisone Acetate			S	Unknown	15 Milligram Daily;		Actavis

Lymphoma	Azathioprine	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Barr
	Mycophenolate Mofetil	S	Unknown			Teva
	Cyclophosphamide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Rituximab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027718	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027724	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799735		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027755	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054667			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown	300 Milligram, Qmo		Not Reported
	Alendronate Sodium Hydrate			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Pruritic; Skin Ulcer	Methotrexate		S	Oral	10 Milligram, Qwk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Prednisone		C	Unknown	10 Milligram, Qd	Not Reported
	Ciclosporin		C	Unknown	150 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028113	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1799246		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Pancytopenia; Product Use In Unapproved Indication	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028114	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028117	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799641			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028121	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1799209		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Sputum Discoloured; Thrombosis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028142	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799154		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr

	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Naproxen	C	Unknown	500 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028164	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	500 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Infliximab			S		5 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported

	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Acetonide	S			Sanofi
	Triamcinolone Acetonide	S	Intra-articular	Unk	Sanofi
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Humira	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Tetanus Immunoglobulin	S	Intravenous (not otherwise specified)	Unk Unk, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028203	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056510		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Parenteral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Actemra	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028756	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200711947		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Aleve			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

Prednisone	C	Unknown		Not Reported
Simponi	C	Unknown		Not Reported
Simponi	C	Subcutaneous		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028809	EXPEDITED (15-DAY)		LT	ES-MYLANLABS-2020M1064705		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Azithromycin			S		500 Mg/24 El Primer Dia Y Luego Baja Dosis A 250 Mg/24		Not Reported
	Lopinavir			S		200/50 Cada 2 Comprimidos Cada 12 Horas		Mylan
	Hidroxicloroquina /00072601/			S		400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028934	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028971	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1799408		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028974	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799732		60 YR	Female	CAN

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

Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028982	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799734		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Golimumab	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Reactine (Cetirizine)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Diclofenac	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028984	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported

	Desoximetasone	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029014	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1799742		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Product Use In Unapproved Indication; Product Use Issue; Septic Shock; Vomiting	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram Daily;		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Oral	250 Milligram Daily;	Not Reported
	Triamcinolone		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029048	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029264	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1799427		41 YR	Female	CAN

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

Diffuse Large B-Cell Lymphoma	Prednisone		S	Unknown	15 Milligram Daily;	Actavis
	Azathioprine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Barr
	Mycophenolate Mofetil		S	Unknown		Teva
	Hydroxychloroquine		S	Unknown	200 Milligram Daily;	Not Reported
	Rituximab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029269	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1799525		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	250 Milligram Daily;		Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029442	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-019506		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S	Minocycline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

Lymphoma; Rheumatoid Arthritis	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029510	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-22198		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective For Unapproved Indication; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Product Use In Unapproved Indication; Purpura; Skin Disorder; Weight Increased	Etanercept			S	Unknown	Unknown		Not Reported
	Amitriptyline			S	Unknown	Unknown		Not Reported
	Amlodipine Besilate			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Bumetanide			S	Unknown	Unknown		Not Reported
	Capsaicin			S	Topical	Unknown		Not Reported
	Cimetidine			S	Unknown	Unknown		Not Reported
	Clonidine			S	Unknown	Unknown		Not Reported
	Diltiazem			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Ibudilast			S	Unknown	Unknown		Not Reported
	Ketamine			S	Topical	Unknown		Not Reported
	Ketamine			S	Oral	Unknown		Not Reported
	Ketamine			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Lidocaine			S	Intravenous (not	Unknown		Not Reported

		otherwise specified)		
Lidocaine	S	Topical	Unknown	Not Reported
Lithium Carbonate	S	Unknown	Unknown	Not Reported
Magnesium	S	Unknown	Unknown	Not Reported
Magnesium	S			Not Reported
Memantine	S	Unknown	Unknown	Not Reported
Metprolol	S	Unknown	Unknown	Not Reported
Mexiletine	S	Unknown	Unknown	Not Reported
Montelukast	S	Unknown	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
N-Acetylcysteine	S	Unknown	Unknown	Not Reported
Naltrexone Hydrochloride	S	Unknown		Not Reported
Palmitoylethanolamide	S	Unknown	Unknown	Not Reported
Pentoxifylline	S	Unknown	Unknown	Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Spironolactone	S	Unknown	Unknown	Not Reported
Vitamin B 2	S	Unknown	Unknown	Not Reported
Vitamin B 2	S			Not Reported
Vitamin C	S	Unknown	Unknown	Not Reported
Calcitonin	C	Unknown	Unknown	Not Reported
Ezetimibe	C	Unknown	Unknown	Not Reported
Trazodone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029685	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-019509		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis;	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Sleep Disorder	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Otezla	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Not Specified	Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029691	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-019510		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Minocycline Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Myochrysine	S	Intramuscular		Not Reported
	Otezla	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Salazopyrin	S	Unknown	Dosage Form: Not Specified	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Dosage Form: Not Specified	Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate	C	Unknown	Dosage Form: Not Specified	Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029751	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799733			Female	CAN

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

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029752	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029823	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799872			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029900	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799810		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine/00072603/	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	S	Unknown	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;	Not Reported
	Risedronate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029911	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799619		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029912	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cymbalta			C	Oral	60 Milligram Daily;		Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029959	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054671		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased;	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported

Therapy Non-Responder	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qmo	Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029998	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799753			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18030062	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799643		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration;	Prednisone			S	Unknown	2.5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr

Wound	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Oral	5 Milligram Daily;	Not Reported
	Humira	C	Unknown		Not Reported
	Indapamide	C	Oral	1.25 Milligram Daily;	Not Reported
	Naproxen	C	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Pantoloc[Pantoprazole]	C	Oral		Not Reported
	Perindopril	C	Oral		Not Reported
	Rituximab	C	Unknown		Not Reported
	Tylenol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18030068	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18030070	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799838		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	12308608	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1745459		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0 Nos		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	11.0 Years	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported

Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Cutaneous	Not Reported

Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Sulfathalidine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Paracetamol	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Duration- 365	Not Reported
Alendronate Sodium	S	Oral		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Oral		Not Reported
Acetaminophen	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported

Hydroxychloroquine Phosphate	S	Oral	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Cosentyx	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Topicort (Canada)	S	Unknown	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
Zyrtec-D	C		Not Reported
Salazopyrin	C		Not Reported
Ibuprofen	C		Not Reported
Leflunomide	C		Not Reported
Lisinopril	C		Not Reported
Vitamin D3	C		Not Reported
Prednisolone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	12889782	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013285		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Product Use In Unapproved Indication; Rash; Red Blood Cell Sedimentation Rate	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	5 Mg, Q.12h		Apotex
	Apo-Leflunomide			S	Unknown	Unk Unk, Bid		Apotex
	Apo-Naproxen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Abnormal; Synovitis	Xeljanz	S	Oral	5 Mg, Q.12h	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Actemra	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported
	Folic Acid	C	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	12913793	EXPEDITED (15-DAY)		DS, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091772		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported

Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram, Qd	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Oral	25 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk, Qwk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Sunconjunctival	Unk	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Methotrexate	S	Oral	1 Gram, Bid	Not Reported
Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Qd	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	1 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	25 Milligram	Not Reported
Kevzara	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported

Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	5 Unk	Not Reported
Prednisone	S	Unknown	1 Milligram	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Cetirizine	S	Oral	10 Milligram	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported

Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cortisone	S	Unknown	25 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Winpred	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported

	Leflunomide	C	Oral	Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	14615992	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0495		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	15569060	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3091		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	15621502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557034-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Etanercept	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	15635328	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Sirukumab	S	Unknown			Not Reported
Stelara	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Minocycline	S	Unknown			Not Reported
Cosentyx	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Morphine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Dilaudid	C	Unknown			Not Reported
Wellbutrin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	15664903	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2571352-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	15751693	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044237		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported

Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting; Weight Increased	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	25 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Indocid [Indometacin]	S	Unknown	Unk	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Folic Acid	S	Unknown	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	200 Milligram, Qd	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported

	Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Cymbalta	C	Oral	30 Milligram, Qd	Not Reported
	Folic Acid Aventis	C	Oral	Unk Unk, Qwk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	B Complex [Vitamin B Complex]	C	Unknown		Not Reported
	Ciprodex [Ciprofloxacin Lactate]	C	Unknown		Not Reported
	Fish Oil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	15852192	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633997-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	15930407	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655633-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate			C	Unknown			Not Reported
	Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	16093680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2709127-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Levothyroxine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	16381300	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2805003-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Form Of Administration-Solution, Single Use Pre-Filled Syringe		Not Reported
	Methotrexate			S	Oral	Form Of Administration-Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form Of Administration-Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Form Of Administration-Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17063605	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17726302	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020922		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder;	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, Every Week		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram Per Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Every Hour		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported

Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Every Week	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Four Times/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Every Hour	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17743424	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437159		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Anakinra			S	Unknown			Not Reported

Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17778166	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505927		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Surgery; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17778542	EXPEDITED (15-DAY)		HO, LT, OT	FR-CELLTRION INC.-2020FR022184			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cough; Covid-19; Covid-19 Pneumonia; Headache; Interstitial Lung Disease; Lung Opacity; Myalgia; Off Label Use; Pyrexia; Respiratory Failure; Therapeutic Response Unexpected	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Four Infusions (375 Mg/M2) Were Weekly		Not Reported
	Rituximab (Unknown)			S	Unknown	Maintenance Therapy; 500 Mg/Maintenance Therapy		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	15 Mg Daily		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg/8 Hour For 10 Days From Day #19		Not Reported
	Nebivolol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17804885	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2602052		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Product Use In Unapproved	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Indication; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17804903	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600819		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single Use Solution		Not Reported
	Enbrel			S	Unknown	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Arava			C				Not Reported
	Codeine			C				Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported

Acetaminophen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17806676	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517470			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17835088	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528681		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Zostavax	C	Subcutaneous	Powder For Suspension	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17835089	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Wellbutrin	C	Oral	Extended Release		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17856403	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200535381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Blood Test Abnormal; Colitis Ulcerative; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Dyschezia; Gait Disturbance; Gastrointestinal Inflammation; Gastrointestinal Mucosal Disorder; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Inflammation; Joint Swelling; Large Intestinal Ulcer; Local Reaction; Loss Of Personal Independence In Daily Activities; Mobility Decreased;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pyoderma Gangrenosum; Rash; Rheumatoid Arthritis; Secretion Discharge; Spontaneous Haemorrhage; Swelling; Syncope; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed; Vomiting	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Aclasta	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Morphine	S	Unknown		Not Reported
	Plantago Afra	S	Unknown		Not Reported
	Entyvio	S	Unknown		Not Reported
	Fentanyl Citrate	S	Intravenous (not otherwise specified)	Liquid Epidural	Not Reported
	Midazolam	S	Intravenous (not otherwise specified)		Not Reported
	Solu-Medrol	S	Intravenous (not otherwise specified)		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Extended Release	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Rabeprazole	C	Unknown		Not Reported
	Asa	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lipitor	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Tums /07357001/	C	Unknown		Not Reported
	Lovenox	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17856877	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200537320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Off Label Use; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Duration: 10 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Duration: 7 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17856930	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200536754		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Hydroxychloroquine /00072603/	S	Unknown			Not Reported
Arava	C	Unknown			Not Reported
Ativan	C	Unknown			Not Reported
Darifenacin	C				Not Reported
Desoximetasone	C	Unknown			Not Reported
Dilaudid	C	Unknown			Not Reported
Diphenhydramine	C	Unknown			Not Reported
Loperamide	C	Unknown			Not Reported
Norflex	C	Unknown			Not Reported
Omnaris	C	Unknown	Metered Dose		Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown			Not Reported
Plantago Ovata	C	Unknown			Not Reported
Synthroid	C	Unknown			Not Reported
Vagifem	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17877106	EXPEDITED (15-DAY)		HO	NVSC2020US158289		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Lymphopenia; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Fingolimod			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17881896	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200607079		36 YR	Female	CAN

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

Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Remicade	S		Janssen
	Actemra	S	Unknown	Not Reported
	Aurothiomalate De Sodium	S	Unknown	Not Reported
	Aurothiomalate De Sodium	S		Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Urelumab	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17886856	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swollen Joint Count Increased; Tender Joint Count Increased	Folic Acid			S	Oral	1 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Apotex
	Naproxen			S	Oral	500 Mg, Bid		Apotex
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Celebrex			S	Oral	100 Mg, Bid		Not Reported
	Ergocalciferol			C	Oral	25 Mg, Qd		Not Reported
	Lansoprazole			C	Oral	30 Mg, Qd		Not Reported
	Paroxetine Hydrochloride			C	Oral	20 Mg, Qd		Not Reported
	Prazosin Hydrochloride			C	Oral	2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17900651	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200616279			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17900743	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-052177			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram Per 12 Hours		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17931126	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Simponi	C	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17935533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012588		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17970192	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200635824			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17974926	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020253501		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		250 Mg, Daily (250 Mg/24 H)		Pfizer
	Venlafaxine Hcl			S		225 Mg/24 H (For More Than 5 Years)		Pfizer
	Venlafaxine Hcl			S		150 Mg, Daily (150 Mg/24h)		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily (400 Mg/24 H)		Not Reported
	Lopinavir/Ritonavir			S		500 Mg, 2x/Day (400/100 Mg/12 H))		Not Reported
	Vortioxetine			S		10 Mg, Daily (10 Mg/24 H)		Not Reported
	Vortioxetine			S				Not Reported

	Trazodone	S	50 Mg, Daily (50 Mg/24 H		Not Reported
	Trazodone	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17982569	NON-EXPEDITED			US-ADVANZ PHARMA-202007006956			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18011881	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006006916			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chills; Disease Recurrence; Fatigue; Gait Disturbance; Gait Inability; Hypoaesthesia; Influenza; Muscle Spasms; Muscular Weakness; Product Counterfeit	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18026619	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral	Dosage Form: Not Specified		Boehringer Ingelheim
	Actemra			S	Subcutaneous	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution		Not Reported

				Subcutaneous	
	Hydroxychloroquine Sulphate	S	Unknown	Dosage Form: Not Specified	Not Reported
	Methotrexate	S	Oral	Dosage Form: Not Specified	Not Reported
	Sulfasalazine	C	Oral	Dosage Form: Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18027294	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18027400	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056434		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)			Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Enbrel		S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18027485	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056925			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18027500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2641866		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 3.0 Months		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Bimatoprost			C	Ophthalmic			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Tylenol Simply Sleep			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18027637	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056448		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported

Arthritis; Stress	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Mefenamic Acid		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Tylenol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18027756	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056401		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Prednisone	C	Oral	10 Milligram, Qwk		Not Reported
Prednisone	C	Oral	6 Milligram, Qwk		Not Reported
Advil [Ibuprofen]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028022	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-03245		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (First Day)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	400 Milligram, Qd		Lupin
	Enoxaparin			S	Unknown	4000 International Unit, Qd		Not Reported
	Enoxaparin			S	Unknown	8000 International Unit, Qd		Not Reported
	Enoxaparin			S	Unknown	Unk (Reduced)		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028253	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-034543		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Lopinavir;Ritonavir			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	20 Milligram		Not Reported
	Dexamethasone			S	Unknown	10 Milligram		Not Reported

	Methylprednisolone		S	Unknown	1 Milligram/Kilogram, Once A Day	Not Reported
	Methylprednisolone		S	Unknown	20 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028299	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056961		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028368	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201803-000916			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Blindness; Bone Disorder; General Physical Condition Abnormal	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.8ml			S	Subcutaneous	40 Mg, 40 Mg,1 In 2		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	Unk,1 In 2 Wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028526	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202007007082			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Counterfeit Product	Hydroxychloroquine Sulfate			S	Unknown	Unk		Concordia

Administered; Gait Disturbance; Systemic Lupus Erythematosus | (Authorized Generic),Plaquenil

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028562	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutanous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028585	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-034490		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028608	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1799874		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported

Hidroxicloroquina Sulfato (2143su)	S	Oral	200 Mg		Teva
Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram		Not Reported
Omeprazol (2141a)	C	Oral	20 Mg		Not Reported
Enoxaparina Sodica (2482so)	C	Subcutaneous	40 Mg		Not Reported
Amlodipino (2503a)	C	Oral	5 Mg		Not Reported
Paracetamol (12a)	C	Intravenous (not otherwise specified)	1 Gram		Not Reported
Hidroxicloroquina Sulfato (2143su)	C	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028733	NON-EXPEDITED			US-ADVANZ PHARMA-202006006858			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Dupixent			S	Subcutaneous	300 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18028787	EXPEDITED (15-DAY)		OT	CA-ACCORD-190115		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S	Unknown			Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

Ciclosporin	S	Oral			Not Reported
Cimzia	S	Subcutaneous	1 Every 1 Weeks		Not Reported
Enbrel	S	Unknown	1 Every 1 Weeks		Not Reported
Gold	S	Unknown			Not Reported
Humira	S	Subcutaneous	1 Every 1 Weeks, Solution Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Lyrica	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituximab	S	Intravenous drip			Not Reported
Simponi	S	Unknown	Solution Subcutaneous		Not Reported
Sulfasalazine	S	Unknown	Not Specified		Not Reported
Piroxicam	C	Unknown			Not Reported
Prednisone	C	Unknown	Not Specified		Not Reported
Azathioprine	S	Intravenous (not otherwise specified)			Not Reported
Azathioprine	S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2640728		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029128	EXPEDITED (15-DAY)		OT	CA-ROCHE-2639244		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo Hydroxyquine			S	Subcutaneous			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Risedronate	C	Oral	Not Reported
	Arava	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029178	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800783			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown	2 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029179	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Prednisone			S	Oral	15 Milligram Daily;		Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029227	EXPEDITED (15-DAY)		OT	CA-ACCORD-190529		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride/Ethanol			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Edetic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Phenylephrine			S	Unknown			Not Reported
	Anti-D Immunoglobulin			S	Unknown			Not Reported

	Sodium Borate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029233	EXPEDITED (15-DAY)		OT	CA-ACCORD-190362		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Eliquis			S	Unknown	2 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029253	EXPEDITED (15-DAY)		OT	CA-ACCORD-190540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling;	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

Pain	Hydroxychloroquine	S	Oral	Every 1 Days		Not Reported
	Actemra	S	Unknown			Not Reported
	Leflunomide	S	Oral	Every 1 Days		Not Reported
	Lyrica	S	Oral	2 Every 1 Days		Not Reported
	Tylenol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029268	EXPEDITED (15-DAY)		OT	CA-ACCORD-190538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029293	EXPEDITED (15-DAY)		DS	CA-ACCORD-190545			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Methotrexate			S	Unknown			Accord
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Cymbalta			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18029347	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800526		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Methotrexate			S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	50 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030339	EXPEDITED (15-DAY)		OT	CA-ACCORD-190367			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030357	EXPEDITED (15-DAY)		OT	CA-ACCORD-189585		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Risedronic Acid			S				Not Reported
	Prednisone			S				Not Reported
	Prednisolone			S				Not Reported
	Plaquenil			S				Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Celebrex			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Desoximetasone			C				Not Reported
	Prednisone			C		1 Every 1 Days		Not Reported
	Leflunomide			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Tylenol			C				Not Reported
	Methotrexate			S				Accord
	Desoximetasone			C		1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030370	EXPEDITED (15-DAY)		OT	CA-ACCORD-190391			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Methotrexate			S	Unknown			Accord
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)			
	Arava	S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days		Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030372	EXPEDITED (15-DAY)		OT	CA-ACCORD-190390		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Methotrexate			S	Oral	1 Every 1 Days		Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide			S	Oral	1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 4 Weeks		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030396	EXPEDITED (15-DAY)		OT	CA-ACCORD-190556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Methotrexate			S	Oral	Frequency: 1 Every 1 Weeks		Accord
	Actemra			S				Not Reported
	Hydroxychloroquine			S	Oral	Frequency: 1 Every 1		Not Reported

				Days		
	Leflunomide	S	Oral	Frequency: 1 Every 1 Days		Not Reported
	Lyrica	S	Oral	Frequency: 2 Every 1 Days		Not Reported
	Tylenol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030400	EXPEDITED (15-DAY)		HO	CA-ACCORD-190566			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate			S	Subcutaneous	1 Every 1 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5.0 Ug/Kg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Every 15 Days		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Every 15 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Every 15 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Every 15 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030407	EXPEDITED (15-DAY)		OT	CA-ACCORD-190394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Accord
	Neoral			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030411	EXPEDITED (15-DAY)		OT	CA-ACCORD-190392			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18030412	EXPEDITED (15-DAY)		OT	CA-ACCORD-190403		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Methotrexate			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031074	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness;	Mobicox			S	Unknown	Dosage Form: Not Specified		Boehringer Ingelheim
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported

Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Depo-Medrol	C	Other	Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown	Dosage Form: Not Specified	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031168	EXPEDITED (15-DAY)		OT	CA-ACCORD-190595			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031214	EXPEDITED (15-DAY)		OT	CA-ACCORD-190455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Leflunomide	S	Unknown	1 Every 1 Days		Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituximab	S	Intravenous drip			Not Reported
Prednisone	C	Unknown			Not Reported
Simponi	C	Unknown	Solution Subcutaneous		Not Reported
Xeljanz	C	Unknown			Not Reported
Arava	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031314	EXPEDITED (15-DAY)		OT	NVSC2020US196643		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Progression; Product Use In Unapproved Indication; Respiratory Failure; Septic Shock	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Norepinephrine			S	Unknown	Unk		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	560 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031362	EXPEDITED (15-DAY)		HO	NVSC2020FR197926		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg Le 20/03/2020 Puis 250 Mg/24 H)		Novartis
	Plaquenil			S	Oral	400mg Le 20/03 A 18h30 Et 400mg Le 21/03 A 8h		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk (32 Mg/42 Ml)		Not Reported
	Cefotaxime			C	Unknown	2000 Mg (2g/8 H)		Not Reported

Bipreterax	C	Oral	Unk (10 Mg/2.5 Mg)	Not Reported
Janumet	C	Unknown	2 Unk (50 Mg/1000 Mg)	Not Reported
Suxamethonii Chloridum	C	Intravenous (not otherwise specified)	Unk	Not Reported
Etomidate	C	Intravenous bolus	30 Mg	Not Reported
Lovenox	C	Subcutaneous	4000 Iu	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Rovamycine	C	Intravenous (not otherwise specified)	6 Miu	Not Reported
Amlodipine	C	Unknown	10 Mg	Not Reported
Sufentanil	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031408	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1.2 Milliliter, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056941		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	640 Milligram, Q4wk		Not Reported
	Arava			S	Oral	Unk, Qwk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Qwk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Qwk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031440	EXPEDITED (15-DAY)		OT	CA-ACCORD-190587		63 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown	2 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate			S	Oral			Accord
	Orencia			S	Intravenous (not otherwise specified)	1 Every 4 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031443	EXPEDITED (15-DAY)		HO	CA-ACCORD-190588		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	1 Every 12 Hours		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

Abnormal; Synovitis	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Unknown		Not Reported
	Xeljanz		S	Oral	2 Every 1 Days	Not Reported
	Leflunomide		C	Unknown		Not Reported
	Hydroxychloroquine		C	Unknown		Not Reported
	Folic Acid		C	Subcutaneous		Not Reported
	Xeljanz		S	Oral	1 Every 12 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031444	EXPEDITED (15-DAY)		OT	CA-ACCORD-190589		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031446	EXPEDITED (15-DAY)		OT	CA-ACCORD-190593			Female	CAN

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

Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis; Rheumatoid Arthritis	Methotrexate		S	Oral		Accord
	Indometacin		S	Oral	1 Every 6 Hours	Not Reported
	Actemra		S	Unknown	1 Every 4 Weeks	Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Plaquenil		S	Oral	1 Every 12 Hours	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	1 Every 8 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056864		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1.2 Milliliter, 1 Every 1 Week		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031645	EXPEDITED (15-DAY)		OT	CA-ACCORD-190388		55 YR	Female	CAN

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

Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide	S	Unknown	1 Every 1 Days		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days		Not Reported
	Xeljanz	C	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031648	EXPEDITED (15-DAY)		OT	CA-ACCORD-190410			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Varenicline			S	Oral	1 Every 1 Days		Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Valtrex			C				Not Reported
	Esomeprazole			C				Not Reported
	Rosuvastatin			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib			C				Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031658	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-191216		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Hyperglycaemia; Mania; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Methylprednisolone			S				Not Reported
	Methylprednisolone			S		High Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031665	EXPEDITED (15-DAY)		OT	CA-ACCORD-190412		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Increased; Stomatitis; Urticaria	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate			S				Not Reported
	Orencia			S				Not Reported
	Minocycline			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Cannabis Sativa			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031666	EXPEDITED (15-DAY)		OT	CA-ACCORD-190429			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Leflunomide	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031829	EXPEDITED (15-DAY)		OT	NVSC2020US196827		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032041	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-22277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Body Height Below Normal; Human Antichimeric Antibody Positive; Joint Destruction; Product Use In Unapproved Indication; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

		otherwise specified)		
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Subcutaneous	Unknown	Not Reported
Anakinra	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral	Unknown	Not Reported
Iv Immune Globulin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Iv Immune Globulin	S	Intravenous (not otherwise specified)		Not Reported
Iv Immune Globulin	S	Intravenous (not otherwise specified)		Not Reported
Iv Immune Globulin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Intravenous drip		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Inhalation	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Prednisone	S	Unknown		Not Reported

Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Sulfasalazine	S	Oral			Not Reported
Triamcinolone	S	Unknown	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown, Suspension Intra-Articular,		Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032467	EXPEDITED (15-DAY)		DE, LT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-053181			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Levofloxacin			S	Unknown	500 Mg/Dia Iv		Zydus Pharm
	Azithromycin			S	Unknown	500 Mg/ Dia		Zydus Pharm
	Kaletra			S	Unknown	532 Mg/133.2 Mg/Dia		Not Reported
	Digoxina			S	Unknown	0.5 Mg/Iv		Not Reported
	Dolquine			S	Unknown	800 Mg Un Dia, 400 Mg 4 Dias		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032468	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-053114			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat Irritation	Azithromycin			S	Unknown	1000 Mg/ 1 Dia Y 500 Mg Resto		Zydus Pharm
	Clarithromycin			S	Unknown	50 Milligram, Qd		Cadila
	Kaletra			S	Unknown	800 Milligram, Qd		Not Reported
	Dolquine			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032496	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514302		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cephalexin Monohydrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032514	EXPEDITED (15-DAY)		OT	NVSC2020ES197577		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Condition Aggravated; Drug	Hydroxychloroquine			S	Unknown	200 Mg, Q12h		Novartis

Ineffective; Lymphopenia; Product Use In Unapproved Indication	Lopinavir,Ritonavir	S	Unknown	400-100 Mg, Q12h	Not Reported
	Ceftriaxone	S	Unknown	2 G, Q24h	Not Reported
	Levetiracetam	S	Unknown	1500 Mg	Not Reported
	Valproate	S	Unknown	1000 Mg	Not Reported
	Dexamethasone	S	Unknown	20 Mg, Q12h	Not Reported
	Enoxaparin	S	Unknown	40 Mg, Q24h, Prophylactic Dose	Not Reported
	Diazepam	S	Unknown	20 Mg	Not Reported
	Lacosamide	S	Unknown	200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057026		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033157	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033412	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800444		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Rheumatoid Arthritis	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Infliximab		S	Unknown		Not Reported
	Infliximab		S			Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram Daily;	Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Atorvastatin		C	Unknown		Not Reported
	Pantoloc [Pantoprazole]		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033439	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral	Dosage Form: Not Specified		Boehringer Ingelheim
	Actemra			S	Subcutaneous	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Dosage Form: Not Specified		Not Reported
	Sulfasalazine			C	Oral	Dosage Form: Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033463	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1800492		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram Daily;		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033556	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals;	Mobicox			S	Unknown	Dosage Form: Not		Boehringer Ingelheim

Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Actemra	S	Subcutaneous	Specified Dosage Form: Not Specified	Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Unknown	Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Humira	C	Unknown	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033778	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800506		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported
Sulfasalazine	S	Unknown	2000 Milligram Daily;		Not Reported
Risedronate Sodium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Topicort	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033877	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Mobicox			S	Unknown	Dosage Form: Not Specified		Boehringer Ingelheim
	Actemra			S	Subcutaneous	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Form Of Admin: Suspension Intrarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Form Of Admin: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034166	EXPEDITED (15-DAY)		HO, OT	CN-BAUSCH-BL-2020-020200		53 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fixed Eruption; Granulocytopenia	Metronidazole			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Cefoxitin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Irregularly		Not Reported
	Prednisone			C		Irregularly For A Long Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034226	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1063948		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd		Mylan
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Mylan
	Hidroxicloroquina Sulfato			S	Oral	400 Milligram, Qd		Mylan
	Omeprazol /00661201/			C	Oral	20 Milligram, Qd		Mylan
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd		Mylan
	Amlodipino /00972401/			C	Oral	5 Milligram, Qd		Mylan
	Paracetamol			C	Intravenous (not otherwise specified)	1 Gram, Q8h		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034240	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1799849			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034350	EXPEDITED (15-DAY)		LT, OT	CA-BAUSCH-BL-2020-019519		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Iron Decreased; Blood Pressure Increased; Headache; Interstitial Lung Disease; Joint Swelling; Monocyte Count Increased; Muscle Spasms; Osteoporosis; Oxygen Saturation Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Walking Aid User	Minocycline			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Accupril			C				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Apo-Atorvastatin			C				Not Reported

	Apo-Hydroxyquine	C		Not Reported
	Apo-Prednisone	C		Not Reported
	Apo-Zopiclone	C		Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Gabapentin	C		Not Reported
	Lactaid	C		Not Reported
	Lactulose	C		Not Reported
	Levemir	C		Not Reported
	Methadone	C		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Nabilone	C		Not Reported
	Novorapid	C		Not Reported
	Pantoprazole	C		Not Reported
	Pms-Cetirizine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034356	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034371	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Mobicox			S	Unknown	Dosage Form: Not Specified		Boehringer Ingelheim
	Actemra			S	Subcutaneous	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	Form Of Admin: Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Subcutaneous	Form Of Admin: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034386	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800478		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Retinal Toxicity	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported
	Azathioprine			S	Unknown	175 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			S	Unknown	162 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Nifedipine			S	Unknown	60 Milligram Daily;		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034387	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800467		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Prednisone			S	Oral	50 Milligram Daily;		Actavis
	Prednisone			S	Oral	20 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Immunoglobulin G (Human)			C	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulin G (Human)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034392	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1800520			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown	2 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034402	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800569		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034403	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034546	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800426		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034549	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1800480		74 YR	Male	CAN

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

Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Prednisone	S	Unknown	10 Milligram Daily;	Actavis
	Methotrexate	S	Unknown		Barr
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034873	EXPEDITED (15-DAY)		OT	CA-ACCORD-190453		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034874	EXPEDITED (15-DAY)		OT	CA-ACCORD-190447			Female	CAN

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

Ineffective; Nausea; Oral Discomfort; Uveitis	Tocilizumab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S		Subcutaneous Solution	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution	Not Reported
	Enbrel	S	Unknown		Not Reported
	Cimzia	C		Subcutaneous Solution, Single-Use Prefilled Syringe	Not Reported
	Prednisone	C	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18035559	DIRECT	Y				35 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	8440193	EXPEDITED (15-DAY)		HO, OT	PT-SANOFI-AVENTIS-2012SA011614		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asthenia; Asthenia; Blood Alkaline	Prednisone			S		Unk		Not Reported
	Prednisolone			S		Unk Unk,Qd		Not Reported
	Alendronate Sodium			S		70 Mg,Qw		Not Reported

Phosphatase Increased; Blood Immunoglobulin M Increased; Bone Erosion; Chest Pain; Cholestasis; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Mucosal Inflammation; Nausea; Osteoporosis; Pyrexia; Rib Fracture; Skin Abrasion; Steatorrhoea; Vomiting; Weight Decreased; Wrist Fracture	Hydroxychloroquine	S		Unk Unk,Qd	Sanofi
	Methotrexate	S		Unk Unk,Qw	Not Reported
	Methotrexate	S		7.5 Mg,Qw	Not Reported
	Sulfasalazine	S		Unk Unk,Qd (Upto 1.5 G Qd)	Not Reported
	Azathioprine	S		Unk Unk,Qd	Not Reported
	Etanercept	S		Unk	Not Reported
	Adalimumab	S		40 Mg,Qow	Not Reported
	Calcium	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	12767724	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076689		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	13359948	EXPEDITED (15-DAY)		OT	CA-SA-2017SA042969			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Qw		Sanofi
	Arava			S	Oral	Unk Unk, Qw		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Qm		Not Reported
	Actemra			S		640 Unk		Not Reported
	Actemra			S		640 Unk		Not Reported
	Apo-Cyclosporine			S	Oral	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qw		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Other	50 Mg, 1 In 1 Week		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Enbrel			S		50 Mg For 4 Yrs		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Humira			S		400 Mg, Qw		Not Reported
	Humira			S		40 Mg,		Not Reported
	Apo-Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not	300 Mg		Not Reported

			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Qw	Not Reported
	Certolizumab	S	Subcutaneous	200 Mg, Qow	Not Reported
	Certolizumab	S		200 Mg, Qow	Not Reported
	Certolizumab	S		200 Mg For 9.0 Month(S) Unk	Not Reported
	Gold	S	Unknown	Unk Unk, Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw	Not Reported
	Infliximab	S		300 Mg, Qw For 2 Years	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk, Unk	Not Reported
	Rituximab	S	Unknown	Unk Unk, Unk	Not Reported
	Orencia	S	Unknown	Unk Unk, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Azathioprine	S	Unknown		Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Ciclosporin	S		Unk	Not Reported
	Imuran [Azathioprine Sodium]	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	C			Not Reported
	Piroxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	14235433	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021665		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Q.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	10 Mg, Qd		Apotex
Leflunomide	S	Unknown	20 Mg, Qd		Apotex
Actemra	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Bid		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
Naproxen	C	Unknown	500 Mg, Qd		Not Reported
Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Methotrexate	C	Oral	25 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	14922263	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044090		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Amlodipine Besilate			S	Oral	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Asacol			S	Unknown	800 Milligram, Tid		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown			Not Reported

Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Mesalazine	S	Oral	800 Milligram, Tid	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Depo-Medrol	C	Intra-articular	120 Milligram	Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Oral	30 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	500 Milligram	Not Reported
	Vitamin D3	C	Unknown	Unk Unk, Qd	Not Reported
	Amlodipine Besilate	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	14971703	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-174527		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Anastrozole			S	Unknown	Unk		Sun
	Docetaxel			S	Unknown	Four 21-Day Cycles		Sun
	Docetaxel			S				Sun
	Hydroxychloroquine			S	Unknown	400 Mg, Daily (7.01 Mg/Kg/Daily)		Ipca
	Cyclophosphamide			S	Unknown	Four 21-Day Cycles		Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	15621423	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557292-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Contraindicated Product Administered; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	S	Oral	Not Reported
Radioactive Gold	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Indometacin	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Cymbalta	C	Oral	Not Reported
Folic Acid	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	15856062	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633852-00			Female	CAN

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

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17038283	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1116759		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction;	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Rosuvastatin Calcium			S	Unknown			Teva
	Piperacillin Sodium /Tazobactam Sodium			S	Unknown			Not Reported
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Cellcept			S	Unknown	1000 Milligram Daily;		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Actonel			C				Not Reported
	Actonel			C	Unknown			Not Reported
	Apo Amlo			C	Unknown			Not Reported
	Apo-K			C	Unknown			Not Reported

Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Diphenhydramine Hydrochloride	C	Oral		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Epoetin Alfa	C	Unknown		Not Reported
	Escitalopram	C	Unknown		Not Reported
	Escitalopram	C	Unknown		Not Reported
	Hydrochlorothiazide	C			Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Ventolin [Salbutamol Sulfate]	C	Unknown		Not Reported
	Tylenol [Paracetamol]	C	Unknown		Not Reported
	Slow-K	C	Unknown		Not Reported
	Risedronate	C			Not Reported
	Risedronate	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoloc [Pantoprazole]	C		40 Milligram Daily;	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown		Not Reported
	Metoprolol	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Methylprednisolone	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Kcl	C	Unknown		Not Reported
	Januvia	C	Unknown		Not Reported
	Insulin Lispro	C			Not Reported
	Insulin Lispro	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17124253	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113880			Unknown	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Anakinra	S	Subcutaneous	150 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk (12.5 Milligram, 4 Every 1 Week)	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Q4wk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Unknown	Unk	Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Oral	10 Milligram, Qd (5 Milligram, 2 Every 1 Day)	Not Reported

Prednisone	S	Oral	3 Milligram, Bid		Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd		Not Reported
Triamcinolone Hexacetonide	S	Unknown			Not Reported
Adalimumab	S	Subcutaneous			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 Gram		Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Unknown	Unk		Not Reported
Triamcinolone Hexacetonide	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17307302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013973			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Bacitracin			S	Unknown	Unk		Not Reported
	Neomycin Sulfate			S	Unknown	Unk		Not Reported
	Polymyxin B Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Bacitracin/ Neomycin/ Polymyxin B			S	Unknown	Unk		Not Reported
	Prednisone			C	Intramuscular	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17315445	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013887			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	1.0 G		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Methotrexate			C		20 Mg, Qd		Not Reported
	Methotrexate			C	Subcutaneous	0.8 Ml, Qd		Not Reported
	Leflunomide			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17424985	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0830		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; No Adverse Event; Rheumatoid Arthritis	Kineret			S	Subcutaneous	100mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celecoxib			S	Unknown			Not Reported

Celecoxib	S		Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Orencia	S		Not Reported
Plaquenil	S		Not Reported
Prednisone	S		Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Gold	S	Intramuscular	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Celecoxib	S	Unknown	Not Reported
Apo-Celecoxib	S		Not Reported
Apo-Leflunomide	S		Not Reported
Rituximab	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17433128	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0819		60 YR	Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Kineret	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Gold	S	Intramuscular	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S		Not Reported
	Imuran	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Azathioprine	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17519533	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Prescribed Underdose; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution, Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Intra-articular	Unknown		Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17580222	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Off Label Use	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17662141	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002380			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd (Fiim-Coated Tablet)		Concordia
	Enoxaparin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17696993	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202004003349			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Off Label Use; Psychotic Disorder	Hydroxychloroquine			S		200 Mg, Bid (Q12h Nasoenteric Probe),		Concordia

			Coated Tablet	
	Hydroxychloroquine	S	200 Mg, Bid (Q12h Nasoenteric Probe), Coated Tablet	Concordia
	Azithromycin	C	Unk	Not Reported
	Ceftriaxone	C	Unk	Not Reported
	Metamizole Sodium	C	Unk	Not Reported
	Sodium Heparin	C	Unk	Not Reported
	Methylprednisolone Sodium Succinate	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported
	Methadone Hydrochloride	C	Unk	Not Reported
	Piperacilina+Tazobactam	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17744175	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-JNJFOC-20200436815		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S				Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Canakinumab	S	Subcutaneous	Not Reported
	Canakinumab	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Vaginal	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported

Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Not Reported
Ilaris	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Cannabis Sativa	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S		Not Reported
Lyrica	C	Unknown	Not Reported
Rituximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17744179	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Finger Deformity; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cosentyx	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17744196	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Sodium Aurothiomalate	S	Intramuscular	Not Reported
Xeljanz	S	Unknown	Not Reported
Acetaminophen	C		Not Reported
Anakinra	C		Not Reported
Ativan	C		Not Reported
Benadryl /00000402/	C		Not Reported
Codeine	C		Not Reported
Darifenacin	C		Not Reported
Darifenacin Hydrobromide	C		Not Reported
Desoximetasone	C		Not Reported
Dilaudid	C		Not Reported
Diphenhydramine	C		Not Reported
Dyclonine Hydrochloride	C		Not Reported
Furosemide	C		Not Reported
Hydromorphone	C		Not Reported
Kadian	C		Not Reported
Loperamide	C		Not Reported
Morphine Sulfate	C		Not Reported
Norflex /00018303/	C		Not Reported
Omnaris	C		Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc /01263204/	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Restasis	C		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C		Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17747074	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437433		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Drug Ineffective; Gastrointestinal Disorder;	Remicade			S	Intravenous (not otherwise specified)			Janssen

Off Label Use; Product Use Issue	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072603/	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Hydroxychloroquine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17792537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20171028710		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral	Not Reported
Celebrex	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Intra-articular	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17885297	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170712977		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17891563	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Humira	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17936648	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-186190		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Muscular Weakness; Somnolence; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	20 Hydroxychloroquine 200 Mg Tablets		Not Reported
	Methotrexate			C		30 Methotrexate 2.5 Mg Tablets		Not Reported
	Prednisone			C		30 Prednisone 10 Mg Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17940934	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012621		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cannabis Sativa			C	Unknown	Unk		Not Reported

Lyrica	C	Unknown	Unk		Not Reported
Orencia	C	Unknown	Unk		Not Reported
Oxycodone	C	Unknown	100 Mg, Unk		Not Reported
Prednisone	C	Unknown	7 Mg, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17954643	EXPEDITED (15-DAY)		OT	CI-ADVANZ PHARMA-202006006754			Unknown	CIV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17976278	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2630327		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Electrocardiogram Qt Prolonged; Hepatitis Toxic; Hyperbilirubinaemia; Hypertransaminasaemia; Intentional Product Use Issue; Ischaemia; Obstructive Airways Disorder; Off Label Use; Peripheral Arterial Occlusive Disease; Secretion Discharge; Thrombosis	Tocilizumab			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18019304	EXPEDITED (15-DAY)		OT	CH-MYLANLABS-2020M1063464		77 YR	Male	CHE

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

Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Klacid	S	Oral	250 Milligram, Total	Mylan
	Kaletra	S	Oral	800 Milligram, Bid	Mylan
	Kaletra	S	Oral	400 Milligram, Bid	Mylan
	Plaquenil /00072603/	S	Oral	800 Milligram, Qd	Mylan
	Plaquenil /00072603/	S	Oral	400 Milligram, Qd	Mylan
	Co-Amoxi	C	Intravenous drip	1.2 Gram, Bid	Mylan
	Tazobac	C		Unk	Mylan
	Fragmin	C		5000 International Unit, Qd	Mylan
	Lasix /00032602/	C		Unk	Mylan
	Plavix	C		Plavix 75mg 1-0-0, Umstellung Auf Aspirin Ab 14.03.2020	Mylan
	Coveram	C		1 Dosage Form, Qd (5/5 Mg)	Mylan
	Torem /01036501/	C		10 Milligram, Qd	Mylan
	Atorvastatine /01326101/	C		40 Milligram, Qd	Mylan
	Zyloric	C		100 Milligram, Qd	Mylan
	Chondrosulf	C		Unk, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18033529	EXPEDITED (15-DAY)		OT	IT-ASTRAZENECA-2020SE87451			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18033824	EXPEDITED (15-DAY)		OT	CA-ACCORD-190427			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18033860	EXPEDITED (15-DAY)		OT	CA-ACCORD-190601			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18033864	EXPEDITED (15-DAY)		OT	CA-ACCORD-190606			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Methotrexate			S	Oral			Accord
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Cimzia			S		1 Every 2 Weeks		Not Reported
	Arava			C				Not Reported
	Depo-Medrol			C				Not Reported
	Pantoprazole			C		1 Every 1 Days		Not Reported
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Cimzia			S		1 Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035220	EXPEDITED (15-DAY)		HO	CA-ROCHE-2642131		52 YR	Female	CAN

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

Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cefazolin	S	Intramuscular	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C		Not Reported
	Naproxen	C		Not Reported
	Viread	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035583	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007105			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tuberculosis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035606	EXPEDITED (15-DAY)		OT	CA-ACCORD-190579		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Oral			Not Reported

Positive; Spinal Column Injury; Synovitis; Treatment Failure	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Mobicox		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035613	EXPEDITED (15-DAY)		OT	CA-ACCORD-190569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus Rash	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Every 1 Days	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036139	EXPEDITED (15-DAY)		DE, LT, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-253683		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Levofloxacin			S	Unknown	500 Mg/Dia Iv ()		Ranbaxy
	Azithromycin			S	Unknown	Unk		Sun
	Kaletra			S	Unknown	532 Mg/133.2 Mg/Dia ()		Not Reported
	Digoxina (770a)			S	Unknown	0.5 Mg/Iv ()		Not Reported
	Dolquine			S	Unknown	800 Mg Un Dia, 400 Mg 4 Dias ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036559	EXPEDITED (15-DAY)		OT	CA-ACCORD-190582		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Azathioprine			S				Not Reported
	Arava			S				Not Reported
	Azathioprine			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

			otherwise specified)	Intravenous
	Sodium Aurothiomalate	S		Not Reported
	Cefalexin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036569	EXPEDITED (15-DAY)		OT	CA-ACCORD-189936			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Mycophenolic Acid			S				Accord
	Methotrexate			S				Accord
	Anakinra			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036636	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-253385		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral	600 Milligram,Mg Every 12 Hours		Sun
	Hydroxychloroquine			S	Oral	400 Milligram, Dailyfor 4 Additional Days		Sun
	Azithromycin			S	Unknown	500 Milligram, Daily		Sun
	Tacrolimus			S	Unknown	5 Milligram, Bid		Not Reported
	Mycophenolate Mofetil			S	Unknown	250 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	5 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036654	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-20K-028-3484280-00		52 YR	Female	CAN

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

Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Cefazolin	S	Intramuscular	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C		Not Reported
	Naproxen	C		Not Reported
	Viread	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036677	EXPEDITED (15-DAY)		OT	CA-ACCORD-190159		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Hydrochlorothiazide			S				Not Reported
Abdominal Pain Upper;	Methotrexate			S				Accord
Arthralgia; Cardiac Failure	Pantoprazole			S				Not Reported
Congestive;	Arava			S				Not Reported
Contraindicated Product	Biaxin			S				Not Reported
Administered; Cough;	Celebrex			S				Not Reported
Diarrhoea; Drug	Cefalexin			S				Not Reported
Hypersensitivity; Drug	Clindamycin			S				Not Reported
Ineffective; Drug	Codeine			S				Not Reported
Intolerance; Dyspnoea;	Enalapril			S				Not Reported
Gastric Disorder;	Enbrel			S				Not Reported
Headache; Hepatic	Fosamax			S				Not Reported
Steatosis; Hypertension;	Gliclazide			S				Not Reported
Loss Of Employment;	Hydralazine			S				Not Reported

Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Hydroxychloroquine	S			Not Reported
	Isoniazid	S			Not Reported
	Levaquin	S			Not Reported
	Lopresor	S			Not Reported
	Losartan	S			Not Reported
	Metoprolol	S			Not Reported
	Moxifloxacin Hydrochloride	S			Not Reported
	Sandoz Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Pariet	S			Not Reported
	Benzylpenicillin	S			Not Reported
	Plaquenil	S			Not Reported
	Tecta	S			Not Reported
	Xeljanz	S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Atenol	C			Not Reported
	Colchicine	C			Not Reported
	Coversyl	C			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	C			Not Reported
	Gold	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Folinic Acid	C			Not Reported
	Prednisone	C			Not Reported
	Ranitidine	C			Not Reported
	Veltassa	C			Not Reported
	Venofer	C		Dosage Form: Solution Intravenous	Not Reported
	Cefalexin	S			Not Reported
	Enalapril	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydrochlorothiazide	S			Not Reported
	Losartan	S			Not Reported
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036853	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020270941		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Kaletra			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	1, Alternate Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036898	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054746		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood	Orencia			S		780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qmo		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Q4wk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported

Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate		S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	12.5 Milligram, Q4wk	Not Reported
	Methotrexate		S	Unknown	12 Milligram, Q4wk	Not Reported
	Methotrexate		S	Unknown	15 Milligram, Q4wk	Not Reported
	Methotrexate		S	Unknown	10 Milligram, Q4wk	Not Reported
	Methotrexate		S	Unknown	17.5 Milligram, Q4wk	Not Reported
	Myochrysine		S	Parenteral	50 Milligram, Qmo	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Milligram	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab		S	Unknown	1000 Milligram, Bid	Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Tocilizumab		S	Unknown	680 Milligram, Q4wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037065	EXPEDITED (15-DAY)		HO	CA-ACCORD-190594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown	1 Every 1 Weeks		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution, 1 Every 2 Weeks		Not Reported
	Leflunomide			S	Oral			Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular, 1 Every 1 Months		Not Reported

Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Orencia		S	Oral	1 Every 1 Weeks	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown	2 Every 1 Days	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Alendronic Acid		C	Unknown	1 Every 1 Weeks	Not Reported
	Ciclosporin		C	Unknown	1 Every 24 Days	Not Reported
	Prednisone		C	Unknown	1 Every 1 Days	Not Reported
	Xeljanz		C	Unknown		Not Reported
	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate		S	Unknown	1 Every 1 Weeks	Accord
	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate		S	Unknown	1 Every 1 Weeks	Accord
	Methotrexate		S	Unknown	1 Every 1 Weeks	Accord
	Actemra		S	Unknown	1 Every 1 Weeks	Not Reported
	Enbrel		S	Unknown	1 Every 1 Weeks	Not Reported
	Methotrexate		S	Oral	1 Every 1 Weeks	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037066	EXPEDITED (15-DAY)		LT	ES-ACCORD-190977		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Hydroxychloroquine			S				Not Reported
	Azithromycin			S		500 Mg / 24 The First Day And Then Lower Dose To 250 Mg / 24		Not Reported
	Lopinavir			S		200/50 Every 2 Tablets Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037329	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2020-057399

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037406	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1062589		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Scarring; Lupus-Like Syndrome	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037441	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Unknown	50 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037688	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-22430		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Cephalexin [Cefalexin]			C	Unknown	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037784	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057387		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037830	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057280		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Dyspnoea; Odynophagia; Rheumatoid Arthritis; Stridor	Orencia			S	Unknown			Bristol Myers Squibb
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037908	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056068		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18038724	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Arava			C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18039279	EXPEDITED (15-DAY)		OT	NVSC2020ES188277		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Amoxicillin,Clavulanic Acid			S	Intravenous (not otherwise specified)	1 Df, Q8h		Novartis
	Azitromicina			S	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Df, Q12h		Not Reported
	Hidroxicloroquina			S	Oral	200 Mg, Q12h		Not Reported
	Atrovent			C	Respiratory (inhalation)	40 Ug, Q6h		Not Reported
	Acido Folico			C	Oral	5 Mg, Q24h (28 Comprimidos)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18039743	EXPEDITED (15-DAY)		OT	NVSC2020FR200786		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	200 Mg, Tid		Novartis
	Azithromycin			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Voriconazole			C	Unknown	Unk		Not Reported
	Piperacilline/Tazobactam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18039753	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800598		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered;	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported

Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S			Not Reported
	Fosamax	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine [Cetirizine]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S			Not Reported
	Diclofenac	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18039819	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1800707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18040233	EXPEDITED (15-DAY)		DE	NVSC2020US201632		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Multiple Organ Dysfunction Syndrome; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18040293	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056956		42 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	15620412	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556731-00		61 YR	Female	CAN

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

Rheumatoid Arthritis	Cimzia	S	Subcutaneous	Single Use Pre Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Vorhyaluronidase Alfa	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	15712495	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587774-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Rituxan	S	Intravenous drip		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	17715964	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020558		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	1.25 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	17894004	EXPEDITED (15-DAY)		DE, HO, OT	ES-AUROBINDO-AUR-APL-2020-029272		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Death; Drug-Induced Liver Injury; Dyspnoea; Electrocardiogram Qt Prolonged; Hepatitis Toxic;	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Hyperbilirubinaemia; Hypertransaminasaemia; Ischaemia; Obstructive Airways Disorder; Off Label Use; Peripheral Arterial Occlusive Disease; Pyrexia; Secretion Discharge; Thrombosis	Hydroxychloroquine	S				Not Reported
	Interferon Beta-1b	S	Subcutaneous	Unk		Not Reported
	Lopinavir/Ritonavir	S	Oral	Unk		Not Reported
	Lopinavir/Ritonavir	S				Not Reported
	Methylprednisolone	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk, 3 Bolus		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	17972341	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-031374		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haematotoxicity; Haemoglobin Decreased; Hypokalaemia; Intentional Overdose; Muscular Weakness; Nausea; Platelet Count Decreased; Somnolence; Treatment Noncompliance; Ventricular Tachycardia; Vomiting	Methotrexate Tablets Usp 2.5mg			S	Unknown	30 Methotrexate 2.5 Mg Tablets		Eugia Pharma
	Methotrexate Tablets Usp 2.5mg			S	Oral	30 Dosage Form, 1 Total		Eugia Pharma
	Hydroxychloroquine			S	Unknown	20 Hydroxychloroquine 200 Mg Tablets		Not Reported
	Hydroxychloroquine			S	Oral	20 Dosage Form, 1 Total		Not Reported
	Prednisone			S	Unknown	Unk (30 Prednisone 10 Mg Tablets)		Not Reported
	Prednisone			S	Oral	30 Dosage Form, 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	17987095	EXPEDITED (15-DAY)		OT	CA-ACCORD-188445		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Prefilled		Not Reported

Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive				Syringe		
	Etanercept	S				Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneou		Not Reported
	Hydroxychloroquine	S				Not Reported
	Leflunomide	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Arthrotec	C				Not Reported
	Azathioprine	C				Not Reported
	Ergocalciferol	C				Not Reported
	Gold	C				Not Reported
	Hydroxychloroquine	S		2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18038870	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2020-03347		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Exposure During Pregnancy; Haemorrhage Intracranial; Moyamoya Disease	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	0.5 Gram, Qd		Lupin
	Prednisolone			S	Unknown	45 Milligram, Qd		Not Reported
	Tacrolimus			S	Unknown	3 Milligram, Qd		Not Reported
	Aspirine			S	Unknown	100 Milligram, Qd		Not Reported
	Heparin			S	Subcutaneous	10000 Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18039054	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03374		79 YR	Female	USA

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

Off Label Use	Hydroxychloroquine	S	Unknown	Unk		Lupin
	Heparin	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18039301	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03450		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Candida Sepsis; Congestive Cardiomyopathy; Off Label Use; Septic Shock	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Tocilizumab			S	Unknown	Unk		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram, Qd		Not Reported
	Enoxaparin			S	Unknown	150 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18039483	EXPEDITED (15-DAY)		OT	CA-ACCORD-190418			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 14 Days Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Sulfasalazine		S	Unknown	Not Specified	Not Reported
	Folic Acid		C	Unknown	Not Specified	Not Reported
	Pantoprazole		C	Unknown		Not Reported
	Tenofovir		C			Not Reported
	Xeljanz		C			Not Reported
	Zopiclone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18039627	EXPEDITED (15-DAY)		OT	CA-ACCORD-190448		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S		Subcutaneous Solution		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S		Subcutaneous Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tenofovir			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18041120	EXPEDITED (15-DAY)		OT	NVSC2020BE200559			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Respiratory Failure; Supraventricular Tachycardia	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18041123	EXPEDITED (15-DAY)		HO	NVSC2020KR200736		60 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive; Decreased Appetite; Feeling Cold; Headache; Product Use In Unapproved Indication; Pyrexia	Hydroxychloroquine Sulfate			S	Unknown	250 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	250 Mg, Qd		Novartis
	Azithromycin			C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18041133	EXPEDITED (15-DAY)		LT	NVSC2020US201638		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2020	18041413	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3486226-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported

Eczema; Sepsis; Urinary Tract Infection	Actemra	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Cannabis Sativa	C		Not Reported
	Dronabinol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	12422597	EXPEDITED (15-DAY)		OT	CA-ROCHE-1766629		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Piroxicam			S	Unknown			Not Reported
	Prednisone			S	Urethral			Not Reported

	Prednisone	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Pregabalin	S	Oral	Not Reported
	Morphine	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	12771269	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076855		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Onychoclasis; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Zostavax	S	Intravenous (not otherwise specified)	Unk		Not Reported
Zostavax	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk		Not Reported
Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Diclofenac [Diclofenac Sodium]	C	Oral	100 Milligram		Not Reported
Diclofenac [Diclofenac Sodium]	C	Oral	5 Milligram, Bid		Not Reported
Cortisone	C	Oral	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	10 Milligram, Bid		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Desoximetasone	C	Oral	5 Milligram, Bid		Not Reported
Desoximetasone	C	Oral	10 Milligram, Qd		Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	13116445	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2017-001069		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Dorzolamide Hydrochloride + Timolol Maleate			S	Ophthalmic			Bausch And Lomb
	Ramipril			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Cosopt	S	Unknown	Not Reported
Codeine Phosphate	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Folic Acid	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Plaquenil	C	Unknown	Not Reported
Levothyroxine	C		Not Reported
Hydroxychloroquine Phosphate	C		Not Reported
Tylenol With Codein	C		Not Reported
Tylenol	C		Not Reported
Paracetamol/Caffeine/Dihydrocodeine	C		Not Reported
Caffeine	C		Not Reported
Methylprednisolone	C		Not Reported
Hydroxychloroquine Sulfate	C		Not Reported
Diphenhydramine	C		Not Reported
Acetaminophen	C		Not Reported
Acetaminophen And Codeine Phosphate	C		Not Reported
Acetaminophen/Caffeine/Dihydrocodeine	C		Not Reported
Acetaminophen /Caffeine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	13121002	EXPEDITED (15-DAY)		OT	CA-SA-2017SA005977			Unknown	CAN

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

Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Arava		S	Unknown	Unk Unk,Unk	Sanofi
	Humira		S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel		S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk Unk,Unk	Not Reported
	Orencia		S	Unknown	Unk Unk,Unk	Not Reported
	Prednisone		S	Unknown	Unk Unk,Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk Unk,Unk	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	13271306	EXPEDITED (15-DAY)		OT	CA-ROCHE-1898404		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Impaired Gastric Emptying; Influenza; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Surgery; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Gold	S	Intramuscular	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Meloxicam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	13868918	EXPEDITED (15-DAY)		OT	CA-ROCHE-1975064			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Cortisone			C				Not Reported
	Gold			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	14298460	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050715		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Peripheral Swelling; Rash; Tendon Disorder; Therapeutic Response Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Bid)		Not Reported
	Methotrexate Sodium			S		20 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S		25 Mg, Weekly (Qw)		Not Reported
	Orencia			S		Unk		Not Reported
	Hydroxychloroquine			C		200 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	14501669	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007157		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Folic Acid			S	Unknown	5 Milligram, 2 Times/Wk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Co Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Co Atenolol			S	Unknown	20 Milligram, Qd		Not Reported
	Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Naprosyne	S	Oral	1000 Milligram, Qd	Not Reported
	Naprosyne	S	Oral	100 Milligram, Qd	Not Reported
	Naprosyne	S	Oral	500 Milligram, Bid	Not Reported
	Palafer Cf	S	Unknown	1 Dosage Form, 1 Every 24 Hrs	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown	40 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Ascorbic Acid	S	Unknown	Unk Unk, Qd	Not Reported
	Actemra	S	Unknown		Not Reported
	Naproxen Sodium	S	Oral	500 Milligram, Bid	Not Reported
	Naproxen Sodium	S	Unknown	100 Milligram, Qd	Not Reported

Naproxen Sodium	S	Unknown	1000 Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Cyclical	Not Reported
Naproxen	S	Oral	500 Milligram, Bid	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	1000 Milligram, Qd	Not Reported
Celecoxib	S	Unknown		Not Reported
Folic Acid	S	Unknown	5 Milligram, Q2wk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	400 Milligram	Not Reported
Folic Acid	S	Unknown	5 Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	40 Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	S	Unknown		Not Reported
Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	1000 Milligram, Qd	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	500 Milligram, Bid	Not Reported

Naprosyn [Naproxen Sodium]	S	Oral	100 Milligram, Qd		Not Reported
Etanercept	S	Subcutaneous	Unk		Not Reported
Palafer	S	Unknown	Unk		Not Reported
Teva Pantoprazole	S	Unknown	40 Milligram, Qd		Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk, Qd		Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, Qd		Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, 1 Every 1 Days		Not Reported
Celebrex	C	Oral	200 Milligram, Qd		Not Reported
Celecoxib	C	Oral	200 Milligram, Qd		Not Reported
Prednisone	C	Intracardiac	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	15100628	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0716		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Vaginal			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

	Azathioprine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Cimzia	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	15626416	EXPEDITED (15-DAY)		HO	CA-SA-2017SA268920			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Synovitis	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg,Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Unknown	Unk		Not Reported

	Orencia	S	Subcutaneous	125 Mg,Qw	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported
	Enbrel	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	15974567	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, Q12h		Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

	Arava			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	16095354	EXPEDITED (15-DAY)		OT	CA-BECTON DICKINSON-2019BDN00113		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Pain; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Chloraprep			S	Topical			Becton Dickinson
	Chlorhexidine			S				Becton Dickinson
	Chlorhexidine Gluconate			S				Becton Dickinson
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S				Not Reported
	Acetaminophen/Oxycodone Hydrochloride			S				Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S				Not Reported
	Act Oxycodone Cr			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month		Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Week(S)		Not Reported
	Actemra			S	Intravenous (not	728 Mg, 1 Every 4		Not Reported

		otherwise specified)	Week(S)	
Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	725 Mg, Every 4 Weeks	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Acetaminophen	S			Not Reported
Chlorhexidine Gluconate Oral Rinse	S			Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S		Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate Sodium	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Oxycodone	S			Not Reported
Oxycodone-Acetaminophen	S			Not Reported
Oxycodone Cr	S			Not Reported
Oxycodone Hydrochloride	S			Not Reported
Oxycodone Terephthalate	S			Not Reported
Periogard	S			Not Reported
Periogard Alcohol Free	S	Buccal		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Sulfamethoxazole	S			Not Reported
Sulfamethoxazole/Trimethoprim	S			Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported

Arava	C		Unk	Not Reported
Cetirizine	C			Not Reported
Cetirizine Hydrochloride	C			Not Reported
Desogestrel/Ethinyl Estradiol	C			Not Reported
Enbrel	C	Subcutaneous		Not Reported
Hydroxychloroquine Phospate	C			Not Reported
Hydroxychloroquine Sulfate	C		400 Mg, 1x/Day	Not Reported
Ibuprofen	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole	C			Not Reported
Pantoprazole Sodium	C			Not Reported
Paracetamol	C			Not Reported
Paracetamol/Codeine	C			Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Prednisone	C	Oral	Unk, 1x/Day	Not Reported
Prednisone	C	Oral	7.5 Mg	Not Reported
Prednisone	C		Unk	Not Reported
Reactine	C		10 Mg, 2x/Day	Not Reported
Reactine	C		Unk	Not Reported
Tylenol	C			Not Reported
Tylenol With Codeine	C			Not Reported
Tylenol #1	C			Not Reported
Zopiclone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	16358401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-049379		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown		Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Isoniazid	S	Unknown		Not Reported
	Lopressor	S	Unknown		Not Reported
	Losartan Potassium	S	Unknown		Not Reported
	Tecta	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Enalapril Maleate	S	Unknown		Not Reported
	Penicillin G [Benzylpenicillin	S	Unknown	Unk	Not Reported

Sodium]				
Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
Clindamycin Hydrochloride	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Venofer	C	Unknown		Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Atenolol	C	Unknown		Not Reported
Colchicine	C	Unknown		Not Reported
Coversyl [Perindopril Erbumine]	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C	Unknown		Not Reported
Levothyroxine Sodium	C	Unknown		Not Reported
Ranitidine	C	Unknown		Not Reported
Veltassa	C	Unknown	Unk	Not Reported
Levothyroxine	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	16370614	EXPEDITED (15-DAY)		HO, OT	SG-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-209316		47 YR	Female	SGP

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

Aspergillus Infection; Urinary Tract Infection Fungal	Hydroxychloroquine	S	Unknown	300 Milligram, Qd Daily	Sun
	Mycophenolate	S	Unknown	1 Gram, Bid Daily	Not Reported
	Prednisolone	S	Oral	5 Milligram, Qd Daily	Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	16718483	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA217214			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	1 G		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Prednisone			C		10 Mg		Not Reported
	Prednisone			C		5 Mg		Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	16820265	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2928046-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Penicillamin (Penicillamine)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17012912	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131752		43 YR	Unknown	CAN

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

Anaphylactic Reaction; Dyspnoea; Rash	Cephalexin	S	Unknown		Not Reported
	Erythromycin	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Erythromycin	S	Unknown		Not Reported
	Actemra	C			Not Reported
	Arava	C			Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported
	Simponi	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17302257	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014160			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Arthralgia; Diarrhoea	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qod		Sanofi
	Hydroxychloroquine Sulfate			S	Subcutaneous	15 Mg, Qw		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17349762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17355394	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020040977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	4 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Weekly		Pfizer
	Leucovorin Calcium			S	Oral	5 Mg, Weekly		Pfizer
	Pantoprazole			S	Oral	1 Df, 1x/Day		Unknown
	Pantoprazole			S	Unknown	Unk		Unknown
	Cosentyx			S	Oral	300 Mg, Monthly		Not Reported
	Diclofenac			S	Oral	Unk, (3 Every 1 Day)		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Meloxicam			S	Oral	7.5 Mg, 1x/Day		Not Reported

Otezla	S	Unknown	Unk		Not Reported
Synthroid	S	Unknown	Unk		Not Reported
Diltiazem Hydrochloride	C	Oral	240 Mg, Unk		Not Reported
Fluticasone Propionate	C	Respiratory (inhalation)	Unk		Not Reported
Mar-Pantoprazole	C	Unknown	Unk		Not Reported
Mometasone Furoate	C	Unknown	Unk		Not Reported
Premarin	C	Unknown	Unk		Not Reported
Salbutamol	C	Respiratory (inhalation)	Unk		Not Reported
Tramadol Hydrochloride	C	Oral	Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17365681	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025307			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Prednisone			S		10 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Df		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C		Not Reported
	Pantoprazole		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17590401	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076268			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17737294	EXPEDITED (15-DAY)		LT, OT	CA-UCBSA-2020017839		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Weekly (Qw)		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Weekly (Qw)		Not Reported
	Humira			S		40 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
Kevzara	S		Unk		Not Reported
Leflunomide	S		Unk		Not Reported
Methotrexate	S	Oral	20 Milligram		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S		Unk		Not Reported
Orencia	S		75 Milligram, Ev 4 Weeks		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sarilumab	S				Not Reported
Simponi	S	Subcutaneous	50 Milligram, Ev 4 Weeks		Not Reported
Sulfasalazine	S		Unk		Not Reported
Tocilizumab	S		Unk		Not Reported
Xeljanz	S	Oral	5milligram, 2 Every 1 Days		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Once Daily (Qd)		Not Reported
Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17754585	EXPEDITED (15-DAY)		HO, OT	CH-ABBVIE-20K-151-3387973-00		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Acute Respiratory Failure; Arteriosclerosis; Blood Potassium Decreased; Blood Potassium Increased; Dysphagia; Dysphonia; Electrocardiogram Qt Prolonged; Hepatic Artery Occlusion; Hepatic Infarction; Hepatocellular	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Perfalgan			S	Intravenous (not otherwise specified)	Maximum 3 Times A Day		Not Reported
	Piperacilline/Tazobactam			S	Intravenous drip			Not Reported
	Zithromax			S	Oral			Not Reported
	Augmentin			C	Intravenous drip			Not Reported

Injury; Hypoperfusion; Intensive Care Unit Acquired Weakness; Liver Function Test Increased; Neuropathy Peripheral; Off Label Use; Off Label Use; Pulmonary Embolism; Splenic Infarction	Ipramol	C	Not Reported
	Temesta	C	Not Reported
	Tavanic	C	Not Reported
	Atracurium	C	Not Reported
	Fentanyl	C	Not Reported
	Dormicum	C	Not Reported
	Phosphate	C	Not Reported
	Colistin	C	Not Reported
	Torasemide	C	Not Reported
	Potassium Chloride	C	Not Reported
	Benerva	C	Not Reported
	Heparin	C	Not Reported
	Solu-Medrol	C	Not Reported
	Relistor	C	Not Reported
	Novasource Gi Control	C	Not Reported
	Ventolin	C	Not Reported
	Movicol	C	Not Reported
	Novorapid	C	Not Reported
	Tobramycin	C	Not Reported
	Amphotericin B	C	Not Reported
	Macrogol	C	Not Reported
	Paracetamol	C	Not Reported
	Tazobac	C	Not Reported
	Potassium Citrate	C	Not Reported
	Salbutamol	C	Not Reported
	Torasemid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17801320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595664		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral	2.0 Years	Not Reported
	Xeljanz	S	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Arava	C			Not Reported
	Lyrica	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17821185	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601280		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired Gastric Emptying; Influenza; Off Label Use; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Product Effect Decreased; Therapeutic Response Decreased	Gold	S	Intramuscular	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Meloxicam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17870632	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011672		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported

Desoximetasone	S	Oral	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Oral	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	1 G, Bid		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17875844	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072603/	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17901370	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200614421		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17921302	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2020-029885		65 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactate Dehydrogenase Increased; Covid-19 Treatment	Azithromycin Generis 500 Mg Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquinol			S	Oral	400 Milligram, Once A Day (400mg 12 / 12h On D1, 200mg 12 / 12h On The Following Days)		Not Reported
	Esomeprazole			C	Oral	Unk		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported
	Cyamemazine			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17968842	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200635890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Skin Ulcer; Thyroid Disorder	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17970189	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200635745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17985963	EXPEDITED (15-DAY)		DE, OT	NVSC2020ES188639		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Death; Dyspnoea; Electrocardiogram Qt Prolonged; Hepatitis Toxic; Hyperbilirubinaemia; Hypertransaminasaemia; Ischaemia; Obstructive Airways Disorder; Off Label Use; Peripheral Arterial Occlusive Disease; Pyrexia; Secretion Discharge; Thrombosis	Interferon Beta-1b			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18012140	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3477008-00		77 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Blood Creatinine Increased; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Klacid			S	Oral	1 Total		Not Reported
	Plaquenil			S	Oral			Not Reported

Plaquenil	S	Oral			Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Intravenous drip	1.2 Gram / 12 H		Not Reported
Tazobac	C				Not Reported
Fragmin	C				Not Reported
Lasix	C				Not Reported
Plavix	C		In The Morning		Not Reported
Aspirin	C				Not Reported
Coveram	C		1 Dosage Forms		Not Reported
Torem	C				Not Reported
Atorvastatin	C				Not Reported
Zyloric	C				Not Reported
Chondrosulf	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18029643	EXPEDITED (15-DAY)		OT	CA-SA-2017SA127669			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg,Qd		Sanofi
	Myochrysine			S	Intramuscular	25 Mg,Qw		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Methotrexate			S	Oral	Unk Unk,Qw		Not Reported
	Leflunomide			S		Unk		Sanofi
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Enbrel			S	Unknown	1000 Mg,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041538	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-209539		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lipodystrophy Acquired; Oedema; Treatment Noncompliance	Prednisone			S	Unknown	Unk		Sun
	Prednisone			S				Sun
	Prednisone			S				Sun
	Hydroxychloroquine			S	Unknown	300 Milligram, Daily		Ipca
	Hydroxychloroquine			S				Ipca
	Hydroxychloroquine			S				Ipca
	Azathioprine			S	Unknown	50-100 Mg/Day		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Potassium Chloride			S	Unknown	180 Meq/Day		Not Reported
	Potassium Chloride			S				Not Reported
	Sodium Bicarbonate			S	Unknown	1960mg/Day		Not Reported
	Sodium Bicarbonate			S				Not Reported
	Amiloride			S	Unknown	10 Milligram, Daily		Not Reported
	Amiloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041554	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-253864		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat Irritation	Azithromycin			S	Unknown	1000 Mg/1 Day And 500 Mg After		Sun
	Clarithromycin			S	Unknown	50 Milligram, Daily		Not Reported
	Kaletra			S	Unknown	800 Milligram, Daily		Not Reported
	Dolquine			S	Unknown	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041630	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03373		70 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041667	EXPEDITED (15-DAY)		DE, OT	AU-ADVANZ PHARMA-202007007145			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Varicella Zoster Vaccine Virus Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisolone			S	Unknown	Low Dose		Not Reported
	Zostavax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041700	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Disability; Gastrointestinal Disorder; Hepatic Enzyme Increased; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)			
	Sulfasalazine	S	Intravenous (not otherwise specified)	500 Milligram		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041735	NON-EXPEDITED			US-ADVANZ PHARMA-202007007131			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041891	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041912	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Psoriasis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041915	EXPEDITED (15-DAY)		HO	AU-ORION CORPORATION ORION PHARMA-20_00009937		61 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Bacteraemia; Acute Kidney Injury; Anaemia; Burkholderia Pseudomallei Infection; Hyperlactacidaemia; Hypotension; Hypoxia; Intervertebral Discitis; Osteomyelitis; Pneumonia	Methotrexate			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041921	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-053415			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Product Use In	Azithromycin			S	Unknown	250 Milligram, Qd		Zydus Pharm
	Venlafaxine			S	Unknown	225 Milligram, Qd		Zydus Pharm

Unapproved Indication	Venlafaxine	S	Unknown	150 Milligram, Qd	Zydus Pharm
	Lopinavir/Ritonavir	S	Unknown	Unk Unk, Bid (400/100)	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Vortioxetine	C		10 Milligram, Qd	Not Reported
	Vortioxetine	C		10 Milligram, Qd (Re-Introduced)	Not Reported
	Trazodone	C		50 Milligram, Qd	Not Reported
	Trazodone	C		50 Milligram, Qd (Re-Introduced)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041957	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-253376		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral	600 Milligram, Every 12 Hours		Sun
	Hydroxychloroquine			S	Oral	400 Milligram, Daily For 4 Additional Days		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18041958	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-253378		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral	600 Milligram, Every 12 Hours For 1 Day		Sun
	Hydroxychloroquine			S	Oral	400 Milligram, Daily For Additional Days		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042001	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-035665		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Venlafaxine			S	Unknown	225 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Lopinavir + Ritonavir			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042057	EXPEDITED (15-DAY)		HO, OT	CH-LUPIN PHARMACEUTICALS INC.-2020-03304		62 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Disease Progression; Lung Infiltration; Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Cefepime			S	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			S	Unknown	Lopinavir 200 Milligrams And Ritonavir 50 Milligrams Twice Daily		Not Reported
	Sirolimus			C	Unknown	Unk		Not Reported
	Sirolimus			C	Unknown	1 Milligram, Qd (Increased To The Usual Dose Of 1 Mg/Day)		Not Reported
	Sirolimus			C	Unknown	Unk (Decreased By 50 Percent))		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Gliclazide			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Vildagliptin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown			Not Reported

	Entecavir		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057823			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042554	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004949		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	65 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	65 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042693	EXPEDITED (15-DAY)		OT	CA-ACCORD-190452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Alendronic Acid			S	Intracavernous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Golimumab	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042695	EXPEDITED (15-DAY)		OT	CA-ACCORD-191110		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042697	EXPEDITED (15-DAY)		OT	CA-ACCORD-191112		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Baclofen			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Gravol			C				Not Reported
	Levaquin			C				Not Reported
	Morphine			C				Not Reported
	Potassium			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C	Ophthalmic	Solution Ophthalmic		Not Reported
	Zingiber Officinale/Zingiber Officinale Rhizome			C				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042698	EXPEDITED (15-DAY)		OT	CA-ACCORD-191111		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042703	EXPEDITED (15-DAY)		OT	CA-ACCORD-191141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Methotrexate			S				Accord
	Ramipril			S	Oral			Accord
	Actemra			S				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S				Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Prednisone			S				Not Reported
	Tylenol			S				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042759	EXPEDITED (15-DAY)		HO	NVSC2020ES199099		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Hydroxychloroquine Sulfate			S	Oral	Segun Documento Aemps Para Covid		Novartis
	Fluconazol			C		200 Mg, Qd (200mg/Día)		Not Reported
	Enoxaparina			C	Subcutaneous	40 Mg, Qd (40mg/24h)		Not Reported
	Azitromicina			C	Oral	500 Mg, Qd (500mg/Dia, 3 Dias)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042810	EXPEDITED (15-DAY)		OT	CA-ACCORD-191154		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042815	EXPEDITED (15-DAY)		OT	CA-ACCORD-191098		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome;	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported

Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Celebrex	S	Oral	Frequency: 2 Every 2 Days	Not Reported
	Enbrel	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Prednisone	C			Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042825	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-191105		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Methotrexate			S		1 Every 1 Weeks		Accord
	Alendronate Sodium/Alendronic Acid			S		1 Every 1 Weeks		Accord
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S		1 Every 1 Months		Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S		2 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S		2 Every 1 Weeks		Not Reported
	Codeine			S				Not Reported
	Leflunomide			S				Not Reported
	Prednisone			C		1 Every 1 Days		Not Reported
	Ciclosporin			C		1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042828	EXPEDITED (15-DAY)		OT	CA-ACCORD-191103		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Arava			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			S	Oral			Accord
	Methotrexate			S	Oral			Accord
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Methotrexate			S	Oral			Accord
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18042907	EXPEDITED (15-DAY)		OT	CA-ACCORD-191070		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous	1 Every 1 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043028	EXPEDITED (15-DAY)		HO	CA-ACCORD-191186			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043032	EXPEDITED (15-DAY)		OT	CA-ACCORD-191048			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Methotrexate			S				Accord
	Leflunomide			S				Not Reported
	Kevzara			S				Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043034	EXPEDITED (15-DAY)		OT	CA-ACCORD-191050		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Accord
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S		1 Every 1 Days	Not Reported
	Humira	S			Not Reported
	Fosamax	S			Not Reported
	Folic Acid	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cetirizine	S			Not Reported
	Arava	S			Not Reported
	Actemra	S			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043051	EXPEDITED (15-DAY)		OT	CA-ACCORD-191058			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine	S	Unknown	Not Reported
	Reactine [Cetirizine]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043067	EXPEDITED (15-DAY)		OT	CA-ACCORD-190112		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Mycophenolic Acid			S				Accord
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Cimzia			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Celebrex			C				Not Reported

	Humira	C	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Methotrexate	C		Frequency: 1 Every 1 Weeks	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Days	Not Reported
	Leflunomide	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043068	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-190113		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Amitriptyline			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Mycophenolic Acid			S	Unknown			Accord
	Montelukast			S	Unknown	Not Specified		Not Reported
	Spironolactone			S	Unknown			Accord
	Pregabalin			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Bumetanide			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Capsaicin			S	Topical			Not Reported
	Cimetidine			S	Unknown	Not Specified		Not Reported
	Clonidine			S	Unknown	Not Specified		Not Reported
	Diltiazem			S	Unknown	Not Specified		Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibudilast			S	Unknown			Not Reported

Ketamine	S	Topical		Not Reported
Lidocaine	S	Intravenous (not otherwise specified)		Not Reported
Lithium	S	Unknown	Not Specified	Not Reported
Magnesium Hydroxide	S	Unknown		Not Reported
Memantine/Memantine Hydrochloride	S	Unknown		Not Reported
Metoprolol	S	Unknown		Not Reported
Mexiletine	S	Unknown		Not Reported
Acetylcysteine	S	Unknown		Not Reported
Naltrexone	S	Unknown	1 Every 24 Hours	Not Reported
Pentoxifylline	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Riboflavin	S	Unknown		Not Reported
Ascorbic Acid	S	Unknown		Not Reported
Trazodone	C	Unknown		Not Reported
Calcitonin	C	Unknown	Not Specified	Not Reported
Ezetimibe	C	Unknown		Not Reported
Ketamine	S	Oral		Not Reported
Ketamine	S	Intravenous (not otherwise specified)		Not Reported
Lidocaine	S	Topical		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown	1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	1 Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043072	EXPEDITED (15-DAY)		OT	CA-ACCORD-190531		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043409	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202007007239			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Colitis; Condition Aggravated; Cough; Covid-19; Covid-19 Pneumonia; Decreased Appetite; Diarrhoea Haemorrhagic; Enterocolitis Haemorrhagic; Frequent Bowel Movements; Nausea; Off Label Use; Oropharyngeal Pain; Vomiting	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Lisinopril			S	Unknown	40 Mg, Qd		Not Reported
	Desvenlafaxine			C		Unk		Not Reported
	Amlodipine			C				Not Reported
	Morphine			C		Unk, Prn (As Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18043777	EXPEDITED (15-DAY)		OT	NVSC2020ES199074		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Azithromycin			S	Unknown	500 Mg, Q24h		Novartis
	Ceftriaxone			S	Intravenous (not	2 G, Q24h		Not Reported

			otherwise specified)		
	Methylpredisolone	S	Unknown	40 Mg, Q24h	Not Reported
	Lopinavir/Ritonavir	S	Oral	2 Df, Q12h	Not Reported
	Dolquine	S	Oral	200 Mg, Q12h	Not Reported
	Metamizole	C	Unknown	Unk	Not Reported
	Clexane	C	Unknown	Unk	Not Reported
	Omeprazol	C	Unknown	Unk	Not Reported
	Metoclopramide	C	Unknown	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044190	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Dronabinol			C	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044230	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057758		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Vestibular Neuronitis	Orencia			S	Unknown			Bristol Myers Squibb

Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Simponi	S	Unknown			Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044332	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056154			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn E			S	Unknown	500 Milligram, Bid		Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045270	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200714200			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)	
	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045279	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801435		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Prednisone			S	Unknown			Actavis
	Metformin Hydrochloride			S	Unknown			Actavis
	Metformin Hydrochloride			S				Actavis
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045496	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801573			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Encephalitis; Meningitis; Synovitis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045543	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058020		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Discomfort; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	1 Dosage Form, Qd		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045738	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801177			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045834	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801995		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)	
Rituximab	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045968	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis; Rheumatoid Arthritis	Indomethacin			S	Oral			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18046081	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200432627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18046133	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056056		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram, Qwk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	1 Every 1 Day		Not Reported
	Ciclosporin			C	Unknown	1 Every 1 Day		Not Reported
	Penicillamine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	6 Milligram, 2 Evevry 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18046177	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802061			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18046253	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056493		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell	Orencia			S	Subcutaneous	750 Milligram		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported

Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18046311	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056509		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18046416	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis; Treatment Failure; Unevaluable Event	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported

	Remicade	S	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18046908	EXPEDITED (15-DAY)		DE, LT	NVSC2020ES199209		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Levofloxacino			S	Unknown	500 Mg (2791a)		Novartis
	Azitromicina			S	Unknown	500 Mg		Not Reported
	Kaletra			S	Unknown	532 Mg/ 133.2 Mg/Dia		Not Reported
	Digoxina			S	Intravenous (not otherwise specified)	0.5 Mg		Not Reported
	Dolquine			S	Unknown	800 Mg Un Dia		Not Reported
	Dolquine			S	Unknown	400 Mg 4 Dias		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	12913694	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053149		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Chondropathy; Condition Aggravated; Diabetes Mellitus; Disability; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Headache; Hypersensitivity; Ill-Defined Disorder; Joint	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Swelling; Liver Function Test Increased; Malaise; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Sarcoidosis; Skin Laceration; Skin Ulcer; Swelling; Tooth Disorder; Tooth Fracture; Treatment Failure; Weight Increased	Actemra	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Crestor	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	S	Oral	0.5 Milligram, Bid	Not Reported
	Rosuvastatin Calcium	S	Oral	5.0 Milligram, Bid	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Rosuvastatin	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rosuvastatin	C	Unknown	0.5 Milligram, Q12h	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Qid	Not Reported
	Coversyl [Perindopril Erbumine]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Allopurinol	C	Unknown	200 Milligram, Qd	Not Reported

	Cephalexin Monohydrate	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	13058749	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015733		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S	Oral	20.0 Mg, Qd		Apotex
	Mefenamic Acid			S	Unknown	400 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	1 Df, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unknown		Not Reported
	Enbrel			S	Unknown	Unk Unk, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Unk (Therapy Duration 730 Unit Unspecified)		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk, Bid		Not Reported
	Advil /00044201/			S	Unknown	400 Mg, Bid		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	13178708	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Infection; Intentional Product Use Issue; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Rheumatoid Arthritis; Syncope; Urticaria	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Qd		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Qwk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Qmo		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 396.0 Nos		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Therapy Duration: 16.0 Years	Not Reported
Xeljanz	S	Oral	Therapy Duration: 7.0 Day(S)	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prevacid	C	Unknown		Not Reported
Prevacid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	13856318	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070219		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Disturbance; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Orencia			S	Oral	200 Milligram, Bid		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Oral	200 Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported

Hydroxychloroquine Phosphate	S	Oral	400 Mg, Qd	Not Reported
Hydroxychloroquine Phosphate	S	Oral	200 Mg, Bid	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Qwk	Not Reported
Apo-Leflunomide	S	Unknown	20.0 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Mg, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram	Not Reported
Sulfasalazine	S	Oral	2 Gram, Bid	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Folic Acid	C	Oral	5 Milligram, Qd	Not Reported
Prednisone	C	Oral		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Milligram, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	15400655	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083412		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Arava			S	Oral	20 Milligram, 1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 1 Every 1 Days		Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram, 1 Every 1 Days		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	15975888	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-016370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qd		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qwk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Gold			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported

Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Certolizumab	S	Unknown	200 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Humira	S	Unknown	400 Mg, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Mg, Q4wk	Not Reported
	Actemra	S	Unknown	640 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	64 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Oral	Unk, Qcycle	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	300 Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Lyrica	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

Azathioprine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulphate	S	Oral	400 Milligram, Qd	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk, Cyclical	Not Reported
Certolizumab Pegol	S	Subcutaneous	200 Milligram, Qwk, Cyclical	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Tocilizumab	S	Unknown	640 Milligram, Qwk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Piroxicam	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Folic Acid	C	Unknown	5 Milligram	Not Reported
Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	16509963	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-212465		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Epstein-Barr Virus Infection Reactivation	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	16567807	EXPEDITED (15-DAY)		DE	CA-GLAXOSMITHKLINE-CA2019AMR122750		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Flovent			S		Unk		Glaxosmithkline
	Losec			S		20 Mg, Unk		Glaxosmithkline
	Metformin			S		500 Mg, Bid		Glaxosmithkline
	Nitrazadon			S		10 Mg, Qd		Glaxosmithkline
	Salmeterol Xinafoate			S		Unk		Glaxosmithkline
	Furosemide			S		40 Mg, Qd		Glaxosmithkline
	Alendronate Sodium			S		70 Mg, We		Not Reported
	Atorvastatin Calcium			S		10 Mg, Qd		Not Reported
	Atrovent			S		Unk		Not Reported
	Ipratropium Bromide + Salbutamol Sulphate			S		Unk		Not Reported
	Lipitor			S		10 Mg, Unk		Not Reported
	Plaquenil			S		300 Mg, Qd		Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Tylenol			S		500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	16736432	EXPEDITED (15-DAY)		OT	NZ-ROCHE-2375240		20 YR	Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Drug-Induced Liver Injury; Groin Abscess; Headache; Liver Function Test Abnormal; Meningitis Aseptic;	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Nausea; Rheumatoid Arthritis	Humira		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Asacol		S	Unknown	6 Tabs	Not Reported
	Asacol		S			Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Prednisone		C			Not Reported
	Sumatriptan		C		As Required According To Dosing Schedule	Not Reported
	Omeprazole		C			Not Reported
	Human Insulin		C			Not Reported
	Amitriptyline		C		Every Night	Not Reported
	Fluoxetine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17033629	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019493322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Pantoprazole			S	Unknown	Unk		Pfizer
	Bisoprolol Fumarate			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported

	Zopiclone		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17396501	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17661978	EXPEDITED (15-DAY)		DS, OT	BR-ADVANZ PHARMA-202003002616			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bedridden; Blindness; Cardiac Disorder; Coma; Corneal Disorder; Decreased Immune Responsiveness; Drug Dependence; Gait Inability; General Physical Health Deterioration; Injury; Limb Discomfort;	Hydroxychloroquine			S	Unknown	Unk, Qod Tablet		Concordia
	Prednisone			C		Unk		Not Reported

Product Use Issue; Renal Disorder; Seizure; Sensory Disturbance; Systemic Lupus Erythematosus; Unevaluable Event

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17675867	EXPEDITED (15-DAY)		OT	NVSC2020DE099946		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma; Granuloma Skin; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate			S	Subcutaneous	15 Mg, Qw		Novartis
	Sulfasalazine			S	Oral	2 Df, Q12h (500mg)		Not Reported
	Prednisolone			S	Oral	4 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd, Two Weeks Before Presentation		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17726929	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004141			Unknown	FRA

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

Acute Kidney Injury; Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	400 Mg, Qd,Film-Coated Tablet	Concordia
	Amoxicillin Clavulanic Acid	C		Unk	Not Reported
	Phocytan	C		Unk	Not Reported
	Tazocilline	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported
	Metoclopramide	C		Unk	Not Reported
	Calcium Chloride	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Unfractionated Heparin	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Loxen	C		Unk	Not Reported
	Urapidil	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Midazolam	C		Unk	Not Reported
	Sufentanil	C		Unk	Not Reported
	Keppra	C		Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Kardegic	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17779230	EXPEDITED (15-DAY)		HO	CA-ROCHE-2593246		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Meningitis; Off Label Use	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported

	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17856321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2613036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Rivotril			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Morphine Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17883838	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-250021		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia;	Azithromycin			S	Oral	500 Milligrams, Daily		Sun

Intentional Product Use Issue; Off Label Use	Hidroxicloroquina Sulfato (2143su)	S	Oral	200 Milligrams, Bid	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	1 Gram, Daily	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	400 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17932932	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020239071		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Electrocardiogram Qt Prolonged; Hepatitis Toxic; Hyperbilirubinaemia; Hypertransaminasaemia; Ischaemia; Obstructive Airways Disorder; Off Label Use; Peripheral Arterial Occlusive Disease; Secretion Discharge; Thrombosis	Azithromycin			S		Unk		Pfizer
	Interferon Beta-1b			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Ceftriaxone			S		Unk		Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17936618	EXPEDITED (15-DAY)		OT	CA-ACCORD-185869		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During	Methotrexate			S	Intra-arterial	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown			Not Reported

Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	1 Every 1 Days	Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Reactine (Cetirizine)	S			Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Tofacitinib	C	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17960047	EXPEDITED (15-DAY)		HO, OT	LT-CELLTRION INC.-2020LT023696			Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Leukopenia; Neurological Symptom; Osteoporosis; Pancytopenia; Thrombocytopenia; Tick-Borne Viral Encephalitis; Transaminases Increased	Infliximab (Unknown)			S		Two Courses, Last Dose Was Injected One Week Earlier (On The 24th Of July 2019)		Not Reported
	Infliximab (Unknown)			S	Unknown	3 Mg/Kg, Two Courses		Not Reported
	Infliximab (Unknown)			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Every 12 Hrs		Not Reported
	Lornoxicam			S	Unknown	8 Mg, Every 12 Hours		Not Reported
	Lornoxicam			S	Unknown	8 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	1/Week (Dose Was Increased To 15 Mg Per Week)		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Decreased Dose		Not Reported
	Methylprednisolone			S	Unknown	12 Mg, Qd		Not Reported
	Verapamil-Trandolapril			S	Unknown	Dose: 240mg/4mg		Not Reported
	Paracetamol			C	Unknown			Not Reported
	Mannitol			C	Unknown			Not Reported
	Ceftazidime			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17966553	EXPEDITED (15-DAY)		OT	NVSC2020ES184110		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Intentional Product Use Issue; Off Label Use	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Q12h		Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Enoxaparin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17971031	EXPEDITED (15-DAY)		HO	NVSC2020IT182318		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Off Label Use	Ritonavir			S	Unknown	Unk		Not Reported
	Ritonavir			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis
	Rivaroxaban			S	Oral	15 Mg, Qd		Not Reported
	Lopinavir			S	Oral	Unk		Not Reported
	Lopinavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17971898	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3466870-00		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Renal Failure	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17991524	EXPEDITED (15-DAY)		DE, HO	NVSC2020ES190698		72 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug-Induced Liver Injury; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

	Interferon Beta-1b	S	Subcutaneous	Unk		Not Reported
	Lopinavir + Ritonavir	S	Unknown			Not Reported
	Ceftriaxone	S	Unknown			Not Reported
	Metilprednisolona	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17993751	EXPEDITED (15-DAY)		LT	NVSC2020BE190264		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemolysis; Off Label Use; Product Use In Unapproved Indication; Renal Ischaemia; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	400 Mg, Qd At 20h		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd At 8h		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Qd At 20h		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Qd At 8h		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Qd At 20h		Novartis
	Hydroxychloroquine			S	Oral	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Clarithromycine			C	Oral	500 Mg, Bid J Per Os		Not Reported
	Januvia			C	Oral	100 Mg, Qd J Per Os		Not Reported
	Metformine			C	Oral	500 Mg, Tid J Per Os		Not Reported
	Zanidip			C	Oral	10 Mg, Qd J Per Os		Not Reported
	Augmentin			C	Intravenous (not otherwise specified)	1 G Q4d Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17995900	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200703520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported

	Cimzia	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Sodium	S	Unknown		Not Reported
	Plaquenil /00072603/	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17995909	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200703518		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18000837	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020260604		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat Irritation	Azithromycin			S		1000 Mg, Daily		Pfizer
	Azithromycin			S		500 Mg, Daily		Pfizer
	Clarithromycin			S		50 Mg, 1x/Day		Not Reported
	Kaletra			S		800 Mg, Daily		Not Reported
	Dolquine			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18001517	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006006905			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Pulmonary Fibrosis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18011979	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006007000			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Hypokinesia; Off Label Use; Product Counterfeit; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18029420	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200703544		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18033480	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1064114		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Drug Interaction; Off Label Use	Everolimus			S		Unk		Not Reported
	Lopinavir/Ritonavir			S		200/100 Mg Twice A Day For 14 Days		Not Reported
	Hydroxychloroquine Sulfate			S		First Day, Then 200mg/12h During 4-9days		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18045858	EXPEDITED (15-DAY)		OT	CA-ACCORD-191172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18045873	EXPEDITED (15-DAY)		OT	CA-ACCORD-191161		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline			S	Oral	1 Every 1 Days		Not Reported
	Esomeprazole			C	Oral	2 Every 1 Days		Not Reported
	Paracetamol			C				Not Reported
	Oxycodone Hydrochloride/Paracetamol			C	Oral			Not Reported
	Naproxen			C	Oral	1 Every 1 Weeks		Not Reported
	Oxycodone			C				Not Reported
	Rosuvastatin			C	Oral			Not Reported
	Valtrex			C	Oral	2 Every 1 Days		Not Reported
	Xeljanz			C				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18046335	EXPEDITED (15-DAY)		DE, OT	AU-LUPIN PHARMACEUTICALS INC.-2020-03362			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Varicella Zoster Vaccine Virus Infection	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisolone			S	Unknown	Low Dose		Not Reported
	Zostavax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18046350	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055995		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Off Label Use; Rheumatoid Arthritis; Synovitis; Vomiting	Orencia			S	Subcutaneous	150 Gram (1 Every 1 Week)		Bristol Myers Squibb
	Orencia			S	Subcutaneous	150 Gram (1 Every 1 Month)		Bristol Myers Squibb
	Celebrex			S	Oral	200 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram (1 Every 1 Week)		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown	500 Milligram (2 Every 1 Days)		Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown	50 Milligram (2 Every 1 Days)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	Unk (1 Every 4 Weeks)		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4mo		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram (2 Every 1		Not Reported

					Days)	
	Xeljanz		S	Oral	5 Milligram, Qd	Not Reported
	Xeljanz		S	Oral	5 Milligram (2 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18046352	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral	6 Milligram, Qd		Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18046362	NON-EXPEDITED			US-GLAXOSMITHKLINE-		46 YR	Female	USA

US2020131227

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasal Operation; Protein Urine Present; Renal Disorder; Sinusitis; Swelling	Benlysta			S	Unknown	1 Df, We		Glaxosmithkline
	Benlysta			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Imuran			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18046468	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201706-003400			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	20 Mg, Unk		Concordia
	Enbrel			S	Subcutaneous	50 Mg, Unk, Subcutaneous Solution		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Neoral			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18046488	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201707-004084			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Hydroxychloroquine			S	Oral	Unk		Concordia
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported

Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Enbrel	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Solution Subcutaneous	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg	Not Reported
	Sulfasalazine	S	Intracardiac	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Naproxen Sodium	C		Unk	Not Reported
	Plaquenil	C		Unk	Not Reported
	Venlafaxine Hydrochloride	C		Unk	Not Reported
	Benadryl	C		Unk	Not Reported
	Reactine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047167	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1802584		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Encephalopathy; Off Label Use; Serotonin Syndrome	Risperidone			S	Unknown	2 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Lopinavir/Ritonavir			S	Unknown	400mg/100mg		Not Reported
	Morphine			S	Unknown	, Single Administration Of Morphine 3mg		Not Reported
	Interferon Beta-1b			S	Unknown	Two Doses On Days 3 And 4		Not Reported
	Tocilizumab			S	Unknown	Single Administration On Day 9		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047169	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1802583		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Encephalopathy; Off Label Use; Serotonin Syndrome; Urinary Retention	Duloxetine			S	Unknown	120 Milligram Daily;		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Lopinavir/Ritonavir			S	Unknown	400mg/100mg, Two Times A Day		Not Reported
	Lithium			S	Unknown	800 Milligram Daily;		Not Reported
	Haloperidol			S	Unknown	2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047175	EXPEDITED (15-DAY)		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-03372		78 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047285	EXPEDITED (15-DAY)		OT	CA-ACCORD-191205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported

	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047292	EXPEDITED (15-DAY)		OT	CA-ACCORD-191174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047296	EXPEDITED (15-DAY)		OT	CA-ACCORD-191176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown	Not Specified		Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported

	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown	Not Specified	Not Reported
	Fosamax		S	Unknown	Not Specified	Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Unknown	Not Specified	Not Reported
	Rituximab		S	Unknown		Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047298	EXPEDITED (15-DAY)		OT	CA-ACCORD-191182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous	Not Specified		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047469	EXPEDITED (15-DAY)		OT	CA-ACCORD-191270		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047480	EXPEDITED (15-DAY)		OT	CA-ACCORD-191357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Hypertension; Inflammation; Joint Lock; Liver Function Test Increased; Mobility Decreased; Musculoskeletal Disorder; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Urticaria	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047485	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-035597			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Off Label Use	Azithromycin			S	Unknown	500 Milligram, Daily		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Unknown	2 Gram For 6 Days		Aurobindo
	Ceftriaxone			S				Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Not Reported
	Hydroxychloroquine			S				Not Reported
	Lopinavir;Ritonavir			S	Unknown	400/100 Milligram Two Times A Day		Not Reported
	Lopinavir;Ritonavir			S				Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047663	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056214		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia			S	Subcutaneous	250 Milligram		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Unknown	2 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047791	EXPEDITED (15-DAY)		OT	CA-ACCORD-191092		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047793	EXPEDITED (15-DAY)		OT	CA-ACCORD-191173		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling;	Methotrexate			S	Subcutaneous			Not Reported

Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18047795	EXPEDITED (15-DAY)		OT	CA-ACCORD-191101		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	Dosage For: Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Indometacin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048022	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056411		58 YR	Female	CAN

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

Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Adalimumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048633	EXPEDITED (15-DAY)		LT	CA-ACCORD-191244			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Kevzara			S	Unknown			Not Reported

Leflunomide	S	Unknown		Not Reported
Orencia	S	Unknown	1 Every 4 Weeks	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	1 Every 4 Weeks	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Xeljanz	S	Oral	2 Every 1 Days	Not Reported
Rabeprazole	C	Oral	1 Every 1 Days	Not Reported
Hydroxychloroquine	S	Oral	2 Every 1 Days	Not Reported
Methotrexate	S	Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048635	EXPEDITED (15-DAY)		OT	CA-ACCORD-191385		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048639	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801797			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neuropathy Peripheral	Ibuprofen			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048654	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802002		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Retinal Toxicity	Mycophenolate Mofetil			S	Unknown	2 Gram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown	100 Milligram Daily;		Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048839	EXPEDITED (15-DAY)		OT	CA-ACCORD-191211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous	Not Specified		Not Reported

Enzyme Increased; Pneumonia	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048841	EXPEDITED (15-DAY)		OT	CA-ACCORD-191210		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral	Not Specified		Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048849	EXPEDITED (15-DAY)		DS	CA-ACCORD-191383		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

Daily Activities; Pain; Synovitis	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048852	EXPEDITED (15-DAY)		OT	CA-ACCORD-191382			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048855	EXPEDITED (15-DAY)		OT	CA-ACCORD-191209		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported

Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	S	Unknown	Not Specified		Not Reported
	Alendronic Acid	C				Not Reported
	Fosamax	C	Unknown			Not Reported
	Ibuprofen	C	Unknown	Not Specified		Not Reported
	Lisinopril	C	Unknown			Not Reported
	Colecalciferol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048858	EXPEDITED (15-DAY)		OT	CA-ACCORD-191207		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Methotrexate			S	Oral			Accord
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			S		1 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S		1 Every 1 Days		Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048859	EXPEDITED (15-DAY)		OT	CA-ACCORD-191266			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported

Erythematosus; Wound	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	Not Specified	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown	Not Specified	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048861	EXPEDITED (15-DAY)		OT	CA-ACCORD-191208			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Accord
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported

Humira	S	Subcutaneous		Not Reported
Fosamax	S			Not Reported
Folic Acid	S			Not Reported
Enbrel	S	Subcutaneous		Not Reported
Cortisone	S	Topical		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cetirizine	S			Not Reported
Arava	S			Not Reported
Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048863	EXPEDITED (15-DAY)		HO	CA-ACCORD-191248			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Prednisone			S	Oral	2 Every 1 Days		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	1 Every 2 Weeks		Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Infliximab			S	Unknown	1 Every 1 Weeks		Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048864	EXPEDITED (15-DAY)		OT	CA-ACCORD-191096		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Methotrexate			S	Subcutaneous			Accord
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048874	EXPEDITED (15-DAY)		OT	CA-ACCORD-191404			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neuropathy Peripheral	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Leflunomide			S	Oral	Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048877	EXPEDITED (15-DAY)		OT	CA-ACCORD-191260			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	C		Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048879	EXPEDITED (15-DAY)		OT	CA-ACCORD-191381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048881	EXPEDITED (15-DAY)		OT	CA-ACCORD-191386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048885	EXPEDITED (15-DAY)		OT	CA-ACCORD-191402			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048886	EXPEDITED (15-DAY)		OT	CA-ACCORD-191254			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Spinal Column Injury; Treatment Failure	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

	Enbrel	S			Not Reported
	Arava	S			Not Reported
	Actemra	S			Not Reported
	Mobicox	C	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048888	EXPEDITED (15-DAY)		OT	CA-ACCORD-191259			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048889	EXPEDITED (15-DAY)		OT	CA-ACCORD-191255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab/Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Reactine (Cetirizine)			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Fosamax			S				Not Reported
	Folic Acid			S				Not Reported
	Enbrel			S				Not Reported
	Desoximetasone			S	Oral			Not Reported

	Cimzia	S	Subcutaneous		Not Reported
	Arava	S			Not Reported
	Prednisone	S			Not Reported
	Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048977	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802311			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049079	NON-EXPEDITED			US-PFIZER INC-2020276427		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049282	EXPEDITED (15-DAY)		OT	CA-ACCORD-191231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia;	Methotrexate			S	Unknown			Accord

Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049283	EXPEDITED (15-DAY)		OT	CA-ACCORD-191229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Actemra			S	Subcutaneous	Solution For Injection/Infusion In A Pre-Filled Syring		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049291	EXPEDITED (15-DAY)		HO	CA-ACCORD-191246			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Endocervical			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049293	EXPEDITED (15-DAY)		OT	CA-ACCORD-191261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Ciclosporin			S	Unknown	Not Specified		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Tofacitinib			S	Unknown			Not Reported

	Paracetamol	C	Not Specified	Not Reported
	Gabapentin	C	Not Specified	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049294	EXPEDITED (15-DAY)		OT	CA-ACCORD-191263		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049301	EXPEDITED (15-DAY)		OT	CA-ACCORD-191232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In	Methotrexate			S	Unknown			Accord
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tofacitinib		S	Unknown	Not Reported
	Paracetamol		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049302	EXPEDITED (15-DAY)		OT	CA-ACCORD-191243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801818			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Ibuprofen			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049861	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056873			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049879	EXPEDITED (15-DAY)		HO, OT	ES-IPCA LABORATORIES LIMITED-IPC-2020-ES-002321			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Reaction With Eosinophilia And	Hydroxychloroquine			S	Unknown	Unk		Ipca

Systemic Symptoms; Hidradenitis; Miliaria

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050145	EXPEDITED (15-DAY)		LT	NVSC2020ES204124		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Novartis
	Azithromycin Dihydrate			S	Unknown	Unk (Every)		Not Reported
	Lopinavir			S	Unknown	Unk (Every)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050183	EXPEDITED (15-DAY)		LT, OT	ES-PFIZER INC-2020274775		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		500 Mg, Daily(500 Mg / 24 The First Day And Then Low Dose At 250 Mg / 24)		Pfizer
	Azithromycin			S		250 Mg, Daily(500 Mg / 24 The First Day And Then Low Dose At 250 Mg / 24)		Pfizer
	Lopinavir			S		2 Df, 2x/Day(200/50 Every 2 Tablets Every 12 Hours)		Not Reported
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050207	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-002298			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Ear Pain; Headache; Nausea; Tension	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Ipca
	Mebeverine			C	Unknown	Unk		Not Reported

	Levothyroxine	C	Unknown	Unk		Not Reported
	Evacal D3 Chewable	C	Unknown	Unk		Not Reported
	Paracetamol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050254	EXPEDITED (15-DAY)		OT	NVSC2020ES200801		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Fingolimod			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050305	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2020AMR130899			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Dizziness; Dyspnoea; Dysstasia; Hunger; Infusion Site Pain; Malaise; Product Availability Issue; Vein Rupture; Vision Blurred; Weight Increased; Wound	Benlysta			S		Unk		Glaxosmithkline
	Reuquinol			S		Unk		Not Reported
	Omeprazole			C		Unk		Glaxosmithkline
	Azathioprine			C		Unk		Glaxosmithkline
	Mycophenolate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050365	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Ibuprofen			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Humira	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Prednisone	C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050746	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050784	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058175		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Desoximetasone	C	Unknown	10 Milligram, Qd		Not Reported
Diclofenac	C	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050792	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802309		71 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050942	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Male	CAN

BMS-2020-058422

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18051086	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1801951		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C	Oral	17 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18051162	EXPEDITED (15-DAY)		HO, LT	CA-JNJFOC-20200722014		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Naproxen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other			Not Reported

Therapeutic Product Effect Decreased; Vomiting	Folic Acid	C		Not Reported
	Triamcinolone Hexacetonide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18051573	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058187			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18051640	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057805		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18051932	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1802735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	200 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18051933	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1802750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Endocervical			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18051998	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056195		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel	Orencia			S	Unknown			Bristol Myers Squibb

Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Intentional Product Use Issue; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Sleep Disorder; Spinal Stenosis	Acetaminophen And Tramadol Hydrochloride	S	Oral		Not Reported
	Aclasta	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	3.0 Years	Not Reported
	Sulfasalazine	S	Unknown	2 Gram, Qd	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Lorazepam	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Methylprednisolone Acetate	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18052409	EXPEDITED (15-DAY)		OT	NVSC2020FR201916		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Erythema; Neuropathy Peripheral	Doxycycline		S	Oral	200 Mg, Qd	Novartis
	Plaquenil		S	Oral	3 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18052528	EXPEDITED (15-DAY)		OT	NVSC2020ES201746		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Omeprazol			C	Oral	20 Mg, Qd		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Mg, Qd		Not Reported
	Amlodipino			C	Oral	5 Mg, Qd		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18052998	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058245		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	10768490	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014100252		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Angioedema; Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Bone Erosion; Diarrhoea; Drug Intolerance; Dyspepsia; Dyspnoea; Feeling Drunk; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Hypoaesthesia; Inappropriate Schedule Of Product Administration; Joint Swelling; Migraine; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Pharyngeal Swelling; Psoriatic Arthropathy; Pyrexia; Rheumatoid Factor Positive; Swelling Face; Synovitis; Synovitis; Uveitis	Enbrel			S	Subcutaneous	50 Mg, One Every One Week		Amgen
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15-20-25 Mg		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400- 300 Mg Die		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Arthrotec			S	Unknown	75 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Lipitor			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Dovobet			C	Topical			Not Reported
	Omeprazole			C	Oral			Not Reported
	Vitamin D2			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	11004684	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1373284-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Arthralgia; Arthralgia; Arthropathy; Arthropathy; Drug Ineffective; Drug Ineffective; Fatigue; Joint Injury; Joint Noise; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	990 Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Rabeprazole			C				Not Reported
	Depo Medrol			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	14921794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044644		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, 2 Every One Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S		200 Mg, 2 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Q2wk		Not Reported

Methotrexate	S	Subcutaneous	20 Mg, Qwk		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, 2 Times/Wk		Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Cyclical		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Prednisone	C	Unknown	20 Mg, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	15102178	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016188			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatotoxicity; Off Label Use; Rash; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	1 Df, Unk		Apotex
	Azathioprine			S	Unknown	1 Df, Unk		Apotex
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Df, Q.Wk.		Not Reported
	Orencia			S	Subcutaneous	1 Dosage Form, Q.Wk.		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	15412889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186047		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure			otherwise specified)	
	Arava	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	16191539	EXPEDITED (15-DAY)		HO, LT, OT	JP-GLAXOSMITHKLINE-JP2019JPN049251		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aplasia Pure Red Cell; Haemolysis; Inappropriate Schedule Of Product Administration	Belimumab			S	Intravenous drip	400mg, Once In Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	400mg, Once In Every Two Weeks		Glaxosmithkline
	Plaquenil			S	Oral	200mg, 400mg Alternate Day		Not Reported
	Prograf			S	Oral	3 Mg, 1d		Not Reported
	Predonine Tablets			C		12 Mg, 1d		Not Reported
	Predonine Tablets			C		13 Mg, 1d		Not Reported
	Predonine Tablets			C		14 Mg, 1d		Not Reported

	Predonine Tablets	C	14 Mg, 1d	Not Reported
	Predonine Tablets	C	22 Mg, 1d	Not Reported
	Predonine Tablets	C	32 Mg, 1d	Not Reported
	Predonine Tablets	C	45 Mg, 1d	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	16691574	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210550			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Arava			S	Oral	Unk		Sanofi
	Plaquenil			S	Oral	Unk		Sanofi
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiosulfate			C				Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17314628	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013892			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug	Leflunomide			S	Unknown	Unk		Sanofi

Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Bid	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Kevzara	S	Unknown	Unk	Sanofi
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S		Unk	Sanofi
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Unknown	750 Mg	Not Reported
	Rituximab	S		1 G	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17759786	EXPEDITED (15-DAY)		HO, OT	IT-SA-2020SA115979			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Off Label Use; Rash Pustular	Clexane T			S	Subcutaneous	6000 Kiu, Qd		Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	10 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	Unk (Dose Reduced)		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Darunavir			S	Oral	800 Mg, Qd		Not Reported

Ritonavir Sandoz	S	Oral	100 Mg, Qd	Not Reported
Folifill	C			Not Reported
Folifill	C			Not Reported
Eutirox	C			Not Reported
Ceftriaxone	C		1 Df, Qd	Not Reported
Lasix [Furosemide]	C			Not Reported
Urbason [Methylprednisolone]	C	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Omeprazole	C			Not Reported
Omeprazole	C			Not Reported
Trelegy Ellipta	C			Not Reported
Trelegy Ellipta	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17780732	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046150		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S		1.25 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17843468	EXPEDITED (15-DAY)		CA	CA-ROCHE-2608792			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Endocervical	Not Reported
	Rituximab	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen	S	Oral	Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Naprosyn	S	Oral	Not Reported
	Leflunomide	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17853747	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3427448-00			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17859022	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1243723		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Intentional Product Use Issue; Off Label Use	Hidroxicloroquina Sulfato (2143su			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gm		Not Reported

	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Enoxaparin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17926056	EXPEDITED (15-DAY)		OT	NVSC2020FR172801		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	1.25 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17942536	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202005006499			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Failure; Cerebellar Tumour; Eyelid Ptosis; Iiird Nerve Paralysis; Myocardial Infarction; Post Procedural Complication; Procedural Headache; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17945539	EXPEDITED (15-DAY)		HO	NVSC2020IT178274		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis
	Apixaban			S	Oral	5 Mg, Qd X 2		Not Reported
	Lopinavir + Ritonavir			S	Oral	1 Df (Unk (Lopinavir 100 Mg, Ritonavir 25 Mg)		Not Reported

	Lopinavir + Ritonavir			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17959247	EXPEDITED (15-DAY)		DE, OT	ES-MYLANLABS-2020M1057164		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Death; Dyspnoea; Electrocardiogram Qt Prolonged; Hepatitis Toxic; Hyperbilirubinaemia; Hypertransaminasaemia; Ischaemia; Obstructive Airways Disorder; Off Label Use; Peripheral Arterial Occlusive Disease; Pyrexia; Secretion Discharge; Thrombosis	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Interferon Beta-1b			S	Subcutaneous	Unk		Mylan
	Ceftriaxone			S	Unknown	Unk		Mylan
	Ceftriaxone			S				Mylan
	Tocilizumab			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17988323	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-188337		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling;	Methotrexate			S	Intra-arterial			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Marijuana	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18004524	EXPEDITED (15-DAY)		HO, OT	NVSC2020FR193517		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Covid-19; Pyrexia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			C	Unknown	8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18028337	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2020267049		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrioventricular Block; Bradycardia; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin	S		Unk	Pfizer
	Azithromycin	S			Pfizer
	Hydroxychloroquine	S		Unk	Not Reported
	Oxygen	C		Unk (Up To A Fio2 Of 0.6)	Not Reported
	Cobicistat/Darunavir/Emtricitabine/Tenofovir	C			Not Reported
	Sarilumab	C	Intravenous (not otherwise specified)	200 Mg	Not Reported
	Sarilumab	C		200 Mg (Second Dose)	Not Reported
	Perindopril	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18028752	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200711949		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18039868	NON-EXPEDITED		OT	US-AMGEN-USASP2020116287		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Injection Site Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18042776	EXPEDITED (15-DAY)		HO, OT	NVSC2020IT182320		79 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction; Labelled Drug-Drug Interaction Medication Error; Off Label Use	Ritonavir			S	Oral	Unk		Not Reported
	Rivaroxaban			S	Oral	15 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lopinavir			S	Oral	Unk		Not Reported
	Lopinavir + Ritonavir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18051384	NON-EXPEDITED			US-AMGEN-USASP2020116114			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use; Toxicity To Various Agents	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	12.5 Mg, Weekly		Not Reported
	Isotretinoin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	100 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18051697	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007193			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Intolerance; Insomnia; Off Label Use; Product Use Issue; Syncope; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg, 3 Times A Week		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Vimovo			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18051750	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-254322		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use	Azithromycin			S	Unknown	400 Milligram, Qd		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid, The First Day		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Enoxaparin			C	Unknown	4000 International Unit, Qd		Not Reported
	Enoxaparin			C	Unknown	8000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18051751	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-254456		60 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Azithromycin			S	Unknown	500 Milligram, Daily		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18051754	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03496		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18051776	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1802680		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hallucinations, Mixed; Hyperglycaemia; Insomnia; Leukocytosis; Mania; Off Label Use	Hydroxychloroquine			S	Unknown			Teva
	Lopinavir-Ritonavir			S	Oral			Not Reported
	Methylprednisolone			S	Unknown	32 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052073	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058610		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Prednisone			S	Unknown	9 Milligram		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

	Xeljanz			S	otherwise specified) Oral	5 Milligram				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052209	EXPEDITED (15-DAY)		OT	CA-ACCORD-191203		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	4 Every 1 Weeks		Not Reported
	Actemra			S	Unknown	1 Every 1 Weeks		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052213	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-191623		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S				Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Azithromycin			S				Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052389	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001287			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling;	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia

Pain	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Lyrica	S	Oral	150 Mg, Bid	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Not Reported
	Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052841	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058636		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052875	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3490417-00		55 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Cholestasis; Diarrhoea; Hepatocellular Injury; Transaminases Increased	Kaletra			S	Oral			Not Reported
	Plaquinol			S	Oral			Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Thiamine			C				Not Reported

	Remifentanil	C			Not Reported
	Methylprednisolone	C			Not Reported
	Furosemide	C			Not Reported
	Esomeprazole	C			Not Reported
	Piperacillin & Tazobactam	C			Not Reported
	Azithromycin	C			Not Reported
	Meropenem	C			Not Reported
	Enoxaparin Sodium	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052943	EXPEDITED (15-DAY)		OT	CA-ACCORD-191256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S				Accord
	Alendronate Sodium/Alendronic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Enbrel			S				Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Leflunomide	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18052951	EXPEDITED (15-DAY)		OT	CA-ACCORD-191505		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	1 Every 1 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053164	EXPEDITED (15-DAY)		OT	NVSC2020ES201432		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Product Use In Unapproved Indication; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Lopinavir,Ritonavir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053341	EXPEDITED (15-DAY)		OT	CA-ACCORD-191433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity;	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported

Treatment Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053344	EXPEDITED (15-DAY)		OT	CA-ACCORD-191435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous	1 Every 1 Months		Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Naproxen			S	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053353	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported

	Enbrel			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053619	EXPEDITED (15-DAY)		OT	CA-ACCORD-191376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Impaired Work Ability; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Accord
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053620	EXPEDITED (15-DAY)		OT	CA-ACCORD-191269		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Methotrexate			S	Unknown	1 Every 2 Weeks, Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous	1 Every 1 Months, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053633	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-191379			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053637	EXPEDITED (15-DAY)		OT	CA-ACCORD-191419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Folic Acid			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053639	EXPEDITED (15-DAY)		OT	CA-ACCORD-191423			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Ibuprofen			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Plaquenil			S				Not Reported
	Sulfasalazine			S				Not Reported

	Prednisone	C	Frequency: 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053641	EXPEDITED (15-DAY)		OT	CA-ACCORD-191502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	1 Every 24 Hours		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 24 Hours		Not Reported
	Sulfasalazine			S	Unknown	1 Every 24 Hours		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053664	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES-1803144		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hidroxicloroquina (2143a)			S	Unknown	400 Mg		Teva
	Azitromicina (7019a)			S	Unknown	500 Mg / 24 The First Day And Then Low Dose At 250 Mg / 24		Not Reported
	Lopinavir (1271a)			S	Unknown	4 Dosage Forms Daily; 200/50 Every 2 Tablets Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053672	EXPEDITED (15-DAY)		OT	GB-ACCORD-191516		45 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Ear Pain; Headache; Nausea; Tension	Hydroxychloroquine	S	Oral		Not Reported
	Mebeverine	C			Not Reported
	Levothyroxine	C			Not Reported
	Evacal D3	C			Not Reported
	Paracetamol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053673	EXPEDITED (15-DAY)		OT	CA-ACCORD-191509		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Increased; Blood Pressure Systolic Increased; Drug Ineffective; Heart Rate Decreased; Infusion Related Reaction; Nasopharyngitis; Stomatitis; White Blood Cell Count Decreased	Methotrexate			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Rosuvastatin			C				Not Reported
	Pantoprazole			C				Not Reported
	Candesartan			C				Not Reported
	Bisoprolol			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053680	EXPEDITED (15-DAY)		OT	CA-ACCORD-191200			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown	1 Every 1 Weeks, Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported

	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Tofacitinib	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053793	EXPEDITED (15-DAY)		OT	CA-ACCORD-191193			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Accord
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine			S				Not Reported
	Arava			S				Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053796	EXPEDITED (15-DAY)		OT	CA-ACCORD-191195		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Ineffective;	Methotrexate			S	Unknown	Not Specified		Accord

Drug Intolerance; Neck Pain; Surgical Failure	Orencia	S	Unknown		Not Reported
	Actemra	S	Unknown	Not Specified	Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Mobicox	C			Not Reported
	Remicade	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053808	EXPEDITED (15-DAY)		HO	CA-ACCORD-191197		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Naproxen			S				Not Reported
	Orencia			S				Not Reported
	Prednisone			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053809	EXPEDITED (15-DAY)		OT	CA-ACCORD-191198		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder;	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported

Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Pain; Pruritus; Rash; Swelling	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Xeljanz	S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053811	EXPEDITED (15-DAY)		OT	CA-ACCORD-191199		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053812	EXPEDITED (15-DAY)		OT	CA-ACCORD-191202			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	1 Every 24 Hours		Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053813	EXPEDITED (15-DAY)		HO, OT	ES-APPCO PHARMA LLC-2087590		75 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Off Label Use; Overlap Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053823	EXPEDITED (15-DAY)		OT	CA-ACCORD-191498		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18053841	EXPEDITED (15-DAY)		OT	CA-ACCORD-191500		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S		1 Every 1 Weeks		Not Reported
	Actemra			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Desoximetasone			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S		1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054077	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03531		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Methotrexate			C	Unknown	15 Milligram, Weekly		Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Prednisone			C	Unknown	40 Milligram And Start A Weekly Taper		Not Reported
	Prednisone			C	Unknown	Back To 10 Milligram		Not Reported
	Prednisone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	3 Milligram, Qd (Slow		Not Reported

Taper)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054080	EXPEDITED (15-DAY)		OT	JP-LUPIN PHARMACEUTICALS INC.-2020-03537			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	200 Milligram, Qd		Lupin
	Methylprednisolone			S	Transplacental	0.5 Gram, Qd		Lupin
	Prednisolone			S	Transplacental	45 Milligram, Qd		Not Reported
	Tacrolimus			S	Transplacental	3 Milligram, Qd		Not Reported
	Aspirine			S	Transplacental	100 Milligram, Qd		Not Reported
	Heparin			S	Transplacental	10000 Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054227	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058595		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054305	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Doxycycline Hyclate			S		50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054332	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not	1000 Milligram		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054441	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1803625		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Neuropathy Peripheral	Doxycycline			S	Oral	200mg		Actavis
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	3 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054745	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058433		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Orencia			S	Unknown			Bristol Myers Squibb
	Doxycycline			S	Unknown	50 Milligram		Not Reported
	Doxycycline			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Oral	4 Dosage Form, Qwk		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Prednisone			C	Unknown	24 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	23 Milligram		Not Reported
	Prednisone			C	Unknown	25 Milligram		Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055010	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056232		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia			S	Subcutaneous	250 Milligram		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	10 Milligram		Not Reported
	Celebrex			S	Unknown	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055160	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056922			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Unk		Not Reported
Zostavax	S	Subcutaneous	500 Milligram		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported
Diclofenac	C	Subcutaneous	Unk		Not Reported
Xeljanz	C	Oral	10 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055207	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1066228		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteonecrosis	Prednisone			S	Unknown	At The Time Of His Visit Patient'S Regimen Included Prednisone 10 Mg		Not Reported
	Prednisone			S	Unknown	Due To Sign Of Active Disease, He Was Told To Increase Prednisone To 40 Mg And Start A Weekly Taper		Not Reported
	Prednisone			S	Unknown	Currently Tolerating A Slow Taper, Now On 3 Mg Per Day		Not Reported
	Azathioprine			S	Unknown	Dose Of Azathioprine Was		Not Reported

					Titrated Up To 100mg Twice A Day	
	Hydroxychloroquine		S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate		S	Unknown	15 Milligram, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055208	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1065671		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Sarilumab			S	Intravenous (not otherwise specified)	200 Milligram		Mylan
	Perindopril			C	Unknown			Mylan
	Cobicistat;Darunavir;Emtricitabine;Tenofovir			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055220	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1065866		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055221	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1065868		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Leflunomide			S	Unknown	Unk				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055600	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1802597		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Decreased; Drug Interaction; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Off Label Use		Teva
	Azithromycin			S	Unknown	250 Milligram Daily; Off Label Use		Not Reported
	Valproate			S	Unknown	1000 Milligram Daily;		Not Reported
	Valproate			S				Not Reported
	Lopinavir/Ritonavir			S	Unknown	400mg/100mg Every 12 H; Lopinavir: 400 Mg; Ritonavir: 100 Mg; Off Label Use		Not Reported
	Meropenem			S	Unknown	Therapy Completed		Not Reported
	Olanzapine			C	Unknown	15 Milligram Daily;		Not Reported
	Olanzapine			C				Not Reported
	Mirtazapine			C	Unknown	15 Milligram Daily;		Not Reported
	Mirtazapine			C				Not Reported
	Metronidazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055638	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1802603		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Venlafaxine			S	Unknown	225 Milligram Daily; Later, Reinitiated At 150 Mg/24h.		Teva
	Venlafaxine			S				Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Off Label Use		Teva
	Azithromycin			S	Unknown	250 Milligram Daily; Off		Not Reported

					Label Use	
	Lopinavir/Ritonavir	S	Unknown	400mg/100mg Every 12h; Lopinavir: 400 Mg; Ritonavir: 100 Mg; Off Label Use		Not Reported
	Vortioxetine	C	Unknown	10 Milligram Daily;		Not Reported
	Vortioxetine	C				Not Reported
	Trazodone	C	Unknown	50 Milligram Daily;		Not Reported
	Trazodone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055832	EXPEDITED (15-DAY)		OT	NVSC2020FR184833		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Scarring; Cutaneous Lupus Erythematosus; Lupus-Like Syndrome; Pericardial Effusion; Synovitis	Adalimumab			S	Subcutaneous	Unk		Novartis
	Adalimumab			S				Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Infliximab			S				Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Methotrexate			C				Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055878	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058597		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C	Oral		Not Reported
	Lyrica	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056353	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1802745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, 1 Every 1 Week		Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown	150 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056398	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802667			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056402	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802337		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Methotrexate	S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr
	Methylprednisolone	S	Unknown	80 Mg		Not Reported
	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Certolizumab Pegol	S	Unknown			Not Reported
	Certolizumab Pegol	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Etanercept	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira	S	Unknown			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056403	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1803011		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Codeine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, 1 Every 1 Week		Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	12.5 Mg, 1 Every 1 Week		Barr

Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	15 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	12 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	12.5 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	15 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	15 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	12 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	12 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	142.8571 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056499	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3490339-00		78 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Kaletra			S	Oral	500 Mg De 12/12h		Not Reported
	Plaquinol			S	Oral	200mg De 12/12h		Not Reported
	Paracetamol			C				Not Reported
	Clarithromycin			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Dopamine			C	Intravenous (not otherwise specified)			Not Reported
	Piperacillin, Tazobactam			C	Intravenous (not otherwise specified)			Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056535	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1802748		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Alendronate Sodium			S	Unknown			Actavis

Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Methotrexate		S	Unknown		Barr
	Codeine		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown	2000 Milligram Daily;	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Ciclosporin		C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056536	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1802543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash	Leflunomide			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Pruritic; Skin Ulcer			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056551	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802317			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056552	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802129		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	7 Milligram Daily;		Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056615	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801346			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased;	Prednisone			S	Unknown			Actavis

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate		S	Unknown	Barr
	Etanercept		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Levothyroxine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056633	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803077		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Adalimumab	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Prednisone	C	Unknown	35 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056640	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Rocuronium			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056674	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801133		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Thyroid Neoplasm	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056698	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801135		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056716	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1801293		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	9 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Dexamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056789	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803042		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Codeine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056839	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802593			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057040	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802432		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Methylprednisolone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057056	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1802695		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Leflunomide	S	Oral		Barr
	Alendronate Sodium	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip	2000 Milligram Daily;	Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

Tocilizumab	S	Unknown			Not Reported
Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057119	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803040		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057129	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803020		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine			S	Unknown			Not Reported
	Sulfamethoxazole /Trimethoprim			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057135	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802709		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug	Codeine			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	Barr
	Actemra	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Adalimumab	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Arava	S	Unknown			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Gold	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
Orencia	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Acetylsalicylic Acid	C	Unknown			Not Reported
Tiaprofenic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057272	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1803046		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Alendronic Acid			S	Unknown			Actavis
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not	2000 Milligram Daily;		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer			otherwise specified)			
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057356	EXPEDITED (15-DAY)		OT	NVSC2020ES200961		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Novartis
	Lopinavir /Ritonavir Sandoz			S	Oral	1 Df, Q12h		Not Reported
	Methylprednisolon			S	Intravenous (not otherwise specified)	60 Mg, Qd		Not Reported
	Dolquine			S	Oral	200 Mg, Q12h		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Pulmicort			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Adiro			C	Unknown	Unk		Not Reported
	Deprax			C	Unknown			Not Reported
	Nolotil /Spa/			C	Unknown	Unk		Not Reported
	Enalapril			C	Unknown	Unk		Not Reported
	Omeprazol			C	Unknown	Unk		Not Reported
	Potasion			C	Unknown	Unk		Not Reported
	Inhixa			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

	Fluimucil		C	Unknown	Unk	Not Reported
	Atorvastatina		C	Unknown	Unk	Not Reported
	Atrovent		C	Unknown	Unk	Not Reported
	Clopidogrel		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057452	EXPEDITED (15-DAY)		OT	NVSC2020FR205616		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057474	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020117992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Arthrotec			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lipitor [Atorvastatin]			S	Oral			Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ventoline [Salbutamol]			C				Not Reported
	Vitamin D2			C	Oral	1000 Dosage Form		Not Reported
	Omeprazole			C	Oral			Not Reported
	Dovobet			C	Topical			Not Reported

	Flovent			C						Not Reported
	Folic Acid			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057514	EXPEDITED (15-DAY)		OT	CA-ASCEND THERAPEUTICS US, LLC-2087639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Estrogel			S	Topical			Ascend
	Estrogel 0.06%			S				Not Reported
	Arava			S	Unknown			Not Reported
	Belimumab (Belimumab), Unknown			S				Not Reported
	Breo Ellipta			S	Respiratory (inhalation)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dexilant			S	Oral			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab (Rituximab), Unknown			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ventolin Hfa			S	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057714	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056964			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia	S	Unknown		Bristol Myers Squibb
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)		Not Reported
	Cortisone Acetate	C	Subcutaneous		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C	Unknown	100 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Unknown	10 Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	11231394	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015064666		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk (Powder For Suspension)		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium	S	Oral	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	11242484	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015065908		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	25 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	11800207	NON-EXPEDITED		OT	CA-AMGEN-KDL279454		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Advil			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Mefenamic Acid			C	Unknown	Unk		Not Reported

Prednisone	C	Oral	10 Milligram, Qd		Not Reported
Prednisone	C	Oral	6 Milligram, Qd		Not Reported
Dequalinium Chloride	C		Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12133375	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016018438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	50 Milligram		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Xeljanz	S	Unknown	5 Nanogram, Bid	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Apo-Minocycline	S	Unknown	50 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Qmo	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	100 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qwk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported

Clavulin	C		Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bcg Vaccine	C	Unknown	Unk	Not Reported
Adalimumab	C		Unk	Not Reported
Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk	Not Reported
Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk	Not Reported
Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
Amoxicillin	C		Unk	Not Reported
Amoxil [Amoxicillin Trihydrate]	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Subcutaneous	400 Milligram	Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
Hydroxychloroquine	C	Unknown	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12244691	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016041934		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergic Oedema; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Joint Surgery; Limb Discomfort; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty;	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

Urticaria			otherwise specified)		
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Naproxen	C		500 Milligram, Bid	Not Reported
	Viread	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12304669	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015013797		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Unknown	Unk	Not Reported
Vioxx	S	Oral	Unk	Not Reported
Vioxx	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Unknown	200 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported
Wellbutrin	C	Oral	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Oral	10 Milligram, Bid	Not Reported
Xeljanz	C	Oral	5 Milliliter, Bid	Not Reported
Xeljanz	C	Oral	10 Milliliter, Bid	Not Reported
Xeljanz	C	Oral	Unk, Bid	Not Reported
Xeljanz	C	Oral	10 Milliliter	Not Reported

	Xeljanz	C	Oral	5 Milliliter		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12330350	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054181		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Elavil			C	Unknown	Unk		Not Reported

Hydrochlorothiazid	C		Unk		Not Reported
Imitrex	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Plaquenil	C	Unknown	Unk		Not Reported
Premarin	C	Unknown	Unk		Not Reported
Tenormin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Sumatriptan Succinate	C	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
Hydrochlorothiazide	C	Unknown	Unk		Not Reported
Amitriptyline	C	Unknown	Unk		Not Reported
Sumatriptan	C		Unk		Not Reported
Tofacitinib	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12370997	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061225		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed Underdose; Product Use Issue; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd (Every 24 Hours)	Not Reported
	Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12494444	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016078553		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen

Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Amgen
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8.0 Milligram	Not Reported
	Actemra	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Rituxan	S	Unknown	1000 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Humira	S	Unknown	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk Unk, Cyclical	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Meloxicam	C	Oral	7.5 Milligram, As Necessary	Not Reported

	Meloxicam	C		7.5 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Prednisolone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12562777	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015105993		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Arthritis; Bronchitis; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Actemra			S		Unk, Qmo (8.0 Mg/Kg)		Not Reported
	Cortisone			C	Oral	5 Milligram		Not Reported
	Desoximetasone			C	Oral	5 Milligram		Not Reported
	Desoximetasone			C	Oral	5 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported

	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12601635	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016096853			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Rituximab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12607819	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016097103		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Risedronate Sodium			S	Unknown	5 Milligram		Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Tylenol			C	Unknown	Unk Unk, As Required		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Cortisone			C		5 Milligram		Not Reported

Cyclobenzaprine	C	Unknown	10 Milligram,1/2 Tablet As Necessary		Not Reported
Cyclobenzaprine	C	Unknown	10 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported
Desoximetasone	C	Unknown	5 Milligram, Qd		Not Reported
Desoximetasone	C	Unknown	5 Milligram		Not Reported
Prednisone Acetate	C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12669990	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016107257		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Nifedipine	C		Unk	Not Reported
	Palafer	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Prednisone	C			Not Reported
	Synthroid	C		Unk	Not Reported
	Toloxin	C		Unk	Not Reported
	Valsartan	C			Not Reported
	Vitamin D3	C		Unk	Not Reported
	Xarelto	C		Unk	Not Reported
	Zinc Citrate	C		Unk	Not Reported
	Atorvastatin Calcium	C		Unk	Not Reported
	Hydrochlorothiazide	C			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	12973995	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016163638		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female;	Enbrel			S	Unknown	Unk		Amgen

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Methotrexate Sodium	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Gold	S	Unknown	50 Milligram, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	8 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram, Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	20 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	13814083	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017109326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported

Decreased	Remicade	S	Unknown	300 Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1000 Milligram	Not Reported
	Cortisone	C		10 Milligram, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	13834570	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017076491		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Arava		S	Oral	Unk	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Mobicox		C	Unknown	15 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	14185047	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017169967		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, Bid		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram, Unk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Leflunomide	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil	S	Intravenous (not otherwise specified)	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	14899274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1570719-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Rituxan	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Zostavax	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Voltaren	C		Not Reported
	Cortisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	14926030	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1851298-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthritis; Back Pain; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Joint Range Of Motion	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	15486757	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016023969		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituximab	S			Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Zostavax	S	Subcutaneous	Unk	Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
Zostavax	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
Voltaren	C	Unknown	100 Milligram, Qd	Not Reported
Cortisone	C		10 Milligram, Qd	Not Reported
Cortisone	C	Oral	Unk	Not Reported
Cortisone	C	Subcutaneous	Unk	Not Reported
Desoximetasone	C	Oral	10 Milligram, Qd	Not Reported
Desoximetasone	C	Unknown	10 Milligram, Qd	Not Reported
Desoximetasone	C	Subcutaneous	Unk	Not Reported
Diclofenac	C	Unknown	100 Milligram, Qd	Not Reported
Diclofenac	C	Unknown	100 Milligram	Not Reported
Diclofenac	C	Subcutaneous	100 Milligram	Not Reported
Cortisone Acetate	C	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Oral	10 Milligram, Bid	Not Reported
Xeljanz	C	Oral	Unk (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17364637	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral	Dose: 3		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Diltiazem Hydrochloride			C	Unknown			Not Reported
	Fluticasone Propionate			C	Respiratory (inhalation)			Not Reported
	Mar-Pantoprazole			C	Unknown			Not Reported
	Mometasone Furoate			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Salbutamol Sulfate			C	Respiratory (inhalation)			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17808273	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17844947	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02444		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Dry Skin; Lip Dry; Sexual Dysfunction	Triamcinolone Acetonide			S		5 Milligram Per Millilitre, Every 6 To 8 Weeks		Lupin
	Triamcinolone Acetonide			S				Lupin
	Finasteride			S	Oral	1.25 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin

	Isotretinoin		S	Oral	30 Milligram, Qd	Not Reported
	Isotretinoin		S	Topical	30 Milligram, Qod	Not Reported
	Tacrolimus		C	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17880240	EXPEDITED (15-DAY)		HO	FR-ROCHE-2613868		4 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Rash	Bactrim			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S	Intravenous drip	Second Administration 08/04/2020		Not Reported
	Piperacilline/Tazobactam			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17930234	EXPEDITED (15-DAY)		HO	NVSC2020IT173875		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Novartis
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17938086	EXPEDITED (15-DAY)		DE	NVSC2020US176448			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cystic Kidney Disease; Delayed Foetal Renal Development;	Leflunomide			S	Transplacental	Maternal Dose: Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unk		Novartis

Dilatation Ventricular; Foetal Exposure During Pregnancy	Prednisone		S	Transplacental	Maternal Dose: Unk	Not Reported
	Levothyroxine Sodium		S	Transplacental	Maternal Dose: Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17950692	EXPEDITED (15-DAY)		HO	CA-ROCHE-2623697		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported

Xeljanz	S	Oral		Not Reported
Acetaminophen	C			Not Reported
Acetaminophen And Codeine Phosphate	C			Not Reported
Celebrex	C			Not Reported
Folic Acid	C	Unknown		Not Reported
Folic Acid	C	Subcutaneous		Not Reported
Metformin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17982796	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020106333		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	10 Milligram, Qwk (2 Days)		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Tofacitinib			C	Unknown	Unk		Not Reported

Cannabis Sativa	C	Unk	Not Reported
Prednisone	C	7 Milligram, Qd	Not Reported
Thyroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17989661	EXPEDITED (15-DAY)			BE-PFIZER INC-2020257294		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		500 Mg		Pfizer
	Azithromycin			S		250 Mg		Pfizer
	Hydroxychloroquine			S		400 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17995054	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES185610		77 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Deep Vein Thrombosis	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Novartis
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ritonavir			S	Oral	50 Mg		Not Reported
	Enoxaparin			S	Subcutaneous	80 Mg		Not Reported
	Anakinra			S	Intravenous drip	100 Mg, Q6h		Not Reported
	Lopinavir			S	Oral	200 Mg		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G		Not Reported
	Valsartan			C	Oral	160 Mg, Qd		Not Reported
	Amlodipine			C	Oral	10 Mg, Qd		Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg		Not Reported
	Piperacillin/Tazobactam			C	Intravenous (not otherwise specified)	Unk		Not Reported

Acetylcysteine	C	Intravenous (not otherwise specified)	1200 Mg		Not Reported
Atorvastatin	C	Oral	70 Mg		Not Reported
Atorvastatin	C	Oral	80 Mg		Not Reported
Iron	C	Intravenous (not otherwise specified)	Unk		Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg		Not Reported
Pentoxifylline	C	Oral	600 Mg, Qd		Not Reported
Clopidogrel	C	Oral	75 Mg		Not Reported
Furosemide	C	Intravenous (not otherwise specified)	20 Mg		Not Reported
Omeprazole	C	Oral	20 Mg, Qd		Not Reported
Omeprazole	C	Oral	20 Mg, Qd		Not Reported
Carvedilol	C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18022968	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799938		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Prednisone			S	Unknown	30 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Rituximab			S	Other			Not Reported
	Tocilizumab			S	Unknown	One Dose		Not Reported
	Bactrim			C	Unknown			Not Reported
	Famotidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18023096	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2020-US-1799961		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Coronavirus Infection; Off Label Use	Prednisone	S	Unknown	Actavis
	Mycophenolate Mofetil	S	Unknown	Teva
	Hydroxychloroquine	S	Unknown	Teva
	Azithromycin	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18023156	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799965		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Prednisone			S	Unknown			Actavis
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18023157	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799962		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18023171	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799967		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off	Prednisone			S	Unknown			Actavis

Label Use	Mycophenolate Mofetil	S	Unknown	Teva
	Mycophenolic Acid	S	Unknown	Teva
	Hydroxychloroquine	S	Unknown	Teva
	Azithromycin	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18023172	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799969		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18026921	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799971		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Prednisone			S	Unknown			Actavis
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolic Acid			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18034044	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799978		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Mycophenolic-Acid			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18034045	EXPEDITED (15-DAY)		DE, HO, LT	US-TEVA-2020-US-1799956		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Coronavirus Infection; Off Label Use	Mycophenolic Acid			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Belatacept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18034046	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1799959		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Coronavirus Infection; Off Label Use	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18034084	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799976		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coronavirus Infection; Off Label Use	Mycophenolate Mofetil		S	Unknown	Teva
	Prednisone		S	Unknown	Actavis
	Hydroxychloroquine		S	Unknown	Teva
	Belatacept		S	Unknown	Not Reported
	Tacrolimus		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18034149	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1799973		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Prednisone			S	Unknown			Actavis
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18034152	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1799980		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use	Prednisone			S	Unknown			Actavis
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18057088	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057740		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort;	Orencia			S	Unknown			Bristol Myers Squibb

Treatment Failure; Uveitis	Adalimumab	S	Unknown	40 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
	Kevzara	S	Unknown		Not Reported
	Methotrexate	S	Unknown	10 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Simponi	S	Unknown		Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18057434	EXPEDITED (15-DAY)		LT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-053766			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Unknown	500 Mg/24 El Primer Dia Y Luego Baja Dosis A 250		Zydus Pharm

				Mg/24	
	Lopinavir	S	Unknown	200/50 Cada 2 Comprimidos Cada 12 Horas	Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S	Unknown	400 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18057459	EXPEDITED (15-DAY)		OT	CA-ACCORD-191718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Chest Pain; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Naproxen			S	Unknown			Not Reported
	Phenobarbital			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18057652	EXPEDITED (15-DAY)		HO, LT, OT	US-APPCO PHARMA LLC-2087644		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haematotoxicity; Hypokalaemia; Intentional Overdose; Muscular Weakness; Nausea; Somnolence; Suicide Attempt; Toxicity To Various Agents; Treatment	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

Noncompliance;
Ventricular Tachycardia;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18057851	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1days		Not Reported
	Atenolol			C	Unknown			Not Reported
	Calcium Folinate			C	Oral	5 Milligram, Qwk		Not Reported
	Celebrex			C	Unknown			Not Reported
	Colchicine			C	Unknown			Not Reported
	Coversyl [Perindopril Arginine]			C	Unknown			Not Reported
	Hctz			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Methotrexate			C	Intramuscular	12.5 Milligram, Qwk		Not Reported
	Ranitidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058002	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1802536		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Codeine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Alendronate Sodium	S	Unknown		Actavis
	Leflunomide	S	Unknown		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S		2000 Milligram Daily;	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058009	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2020-035711		52 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pneumonia; Product Use In Unapproved Indication	Azithromycin	S	Unknown	500 Milligram (On The First Day))	Aurobindo
	Azithromycin	S	Unknown	250 Milligram, Daily	Aurobindo
	Hydroxychloroquine	S	Unknown	400 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058143	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-036038		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, 1 Total Single		Aurobindo
	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Levomepromazine			S	Unknown	Unk		Not Reported
	Zuclopenthixol			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Milligram, Once A Day		Not Reported
	Alimemazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058164	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-036048			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Off Label Use	Azithromycin			S	Oral	500 Milligram, 1 Total (Single)		Aurobindo
	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Oral	600 Milligram, Once A Day (200 Mg/L, Tid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058221	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-		67 YR	Female	FRA

APL-2020-036155

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngeal Oedema; Tongue Oedema	Perindopril			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Cortancyl			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058255	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056932		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1.2 Milliliter, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058305	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020117994		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Enbrel		S	Unknown	Unk	Amgen
	Actemra		S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Calcium/Vitamin D3		C			Not Reported
	Hydrocortisone		C		Unk Unk, Bid	Not Reported
	Pantoloc [Pantoprazole]		C			Not Reported
	Prednisone		C		20 Milligram, Qd	Not Reported
	Tylenol Arthritis Pain		C		2 Dosage Form, Bid	Not Reported
	Xarelto		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058308	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-03583		34 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate Tablets			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Unknown	200 Milligram, Qd (200 Mg/2 Tablets Per Day)		Lupin
	Tocilizumab			S	Parenteral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058310	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-MAPI_00010642			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	300 Mg, Weekly		Concordia
	Enbrel			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Weekly		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Arava	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058326	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201701-000492			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058346	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2020-020338		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged	Venlafaxine			S	Unknown	Used More Than Five Years		Not Reported
	Venlafaxine			S	Unknown	Re-Introduced With Decreased Dose		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown	400/100 Mg		Not Reported
	Vortioxetine			S	Unknown	Five Months Prior		Not Reported

				Consultation		
	Vortioxetine	S	Unknown	Re-Introduced		Not Reported
	Trazodone	S	Unknown	Five Months Prior Consultation		Not Reported
	Trazodone	S	Unknown	Re-Introdoced		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058367	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1066158		79 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use; Transaminases Increased	Lopinavir/Ritonavir			S	Oral	2 Cp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 12/12h Em D0		Mylan
	Ipratropium Bromide			C	Respiratory (inhalation)	4 Dosage Form, Qd		Mylan
	Omeprazole			C	Oral	20 Milligram, Qd		Mylan
	Enoxaparin Sodium			C		40 Milligram, Qd		Mylan
	Enoxaparin Sodium			C		20 Milligram, Qd		Mylan
	Irbesartan			C	Oral	150 Milligram, Qd		Mylan
	Amlodipine			C	Oral	5 Mg1xdia (21-03 A 23-03) E 2,5 Mg (23-03)		Mylan
	Bisoprolol			C	Oral	2.5 Milligram, Qd		Mylan
	Trazodone			C	Oral	150 Milligram, Qd		Mylan
	Ceftriaxone			C	Intravenous (not otherwise specified)	2000 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058384	EXPEDITED (15-DAY)		HO	IT-LUPIN PHARMACEUTICALS INC.-2020-03477		50 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

	Lopinavir/Ritonavir	S	Unknown	Unk	Not Reported
	Anakinra	S	Intravenous (not otherwise specified)	200 Milligram, Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Qid (Every 6 Hour)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058404	EXPEDITED (15-DAY)		HO, OT	NVSC2020FR205353		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Single		Novartis
	Azithromycin			S	Oral	250 Milligram, Qd		Novartis
	Levomepromazine			S	Unknown	Unk		Not Reported
	Zuclopenthixol			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg/L, Tid		Not Reported
	Alimemazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058460	EXPEDITED (15-DAY)		HO	TR-LUPIN PHARMACEUTICALS INC.-2020-03483		61 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Twice On The First Day)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (Maintenance Dose)		Lupin
	Oseltamivir Phosphate			S	Unknown	75 Milligram, Bid		Lupin
	Favipiravir			S	Unknown	1600 Milligram, Bid (Twice On The First Day)		Not Reported
	Favipiravir			S	Unknown	600 Milligram, Bid (Maintenance Dose)		Not Reported
	Prednisolone			S	Intravenous (not	40 Milligram		Not Reported

			otherwise specified)			
	Ranitidine	S	Unknown	50 Milligram		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Secukinumab	C	Unknown	Unk		Not Reported
	Enoxaparin Sodium	C	Unknown	60 Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058663	EXPEDITED (15-DAY)		OT	CA-ACCORD-191735		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S	Oral	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Tylenol			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058670	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-191779		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Ramipril			S		1 Every 1 Days		Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 1 Days		Not Reported
	Prednisone			S		1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Levothyroxine			S				Not Reported

Hydroxychloroquine	S		1 Every 1 Days	Not Reported
Humira	S			Not Reported
Folic Acid	S			Not Reported
Enbrel	S			Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	2 Every 1 Days	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Every 4 Weeks	Not Reported
Levothyroxine	S		1 Every 1 Days	Not Reported
Codeine	S			Not Reported
Caffeine/Paracetamol	C			Not Reported
Caffeine/Codeine Phosphate/Paracetamol	C			Not Reported
Hydroxychloroquine	C			Not Reported
Paracetamol	C			Not Reported
Methylprednisolone	C			Not Reported
Paracetamol	C			Not Reported
Diphenhydramine	C			Not Reported
Plaquenil	C			Not Reported
Codeine Phosphate/Paracetamol	C			Not Reported
Hydroxychloroquine	C		1 Every 1 Days	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058717	EXPEDITED (15-DAY)		OT	CA-ACCORD-192056			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058729	EXPEDITED (15-DAY)		OT	CA-ACCORD-192055		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous. 2 Every 1 Week		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rho D Immune Globulin			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous	2 Every 1 Days		Not Reported
	Lipitor			C	Oral	1 Every 1 Weeks		Not Reported
	Ibuprofen			C				Not Reported
	Celebrex			C	Oral			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Prednisone			C	Oral	1 Every 1 Week		Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058910	EXPEDITED (15-DAY)		OT	NVSC2020ES201092		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat	Azithromycin			S	Unknown	1000 Mg, Qd (Y 500 Mg Resto)		Novartis

Irritation	Clarithromycin	S	Unknown	50 Mg, Qd		Not Reported
	Kaletra	S	Unknown	800 Mg, Qd		Not Reported
	Dolquine	S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059093	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059149		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Milligram		Not Reported
	Folic Acid			C	Unknown	10 Milligram, Qd		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059156	EXPEDITED (15-DAY)		LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254240		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S	Unknown			Sun
	Azithromycin			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059170	EXPEDITED (15-DAY)		LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254238		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Sun
	Azithromycin			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060284	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-02606			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	600 Milligram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd (Day 1)		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd (Day 2 To 5)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060470	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059118		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Etanercept	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd		Not Reported
Methotrexate	S	Oral	65 Milligram, Qwk		Not Reported
Methotrexate	S	Subcutaneous	65 Milligram, Qwk		Not Reported
Methotrexate	S	Unknown	60 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060734	NON-EXPEDITED		DS, OT	CH-LUPIN PHARMACEUTICALS INC.-2020-02778		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Overdose	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (Daily Dose 9.5mg/Kg)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060735	NON-EXPEDITED		HO, OT	CH-LUPIN PHARMACEUTICALS INC.-2020-02638		68 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis	Hydroxychloroquine			S	Unknown	600 Milligram, Single		Lupin
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060862	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Orencia	S	Unknown		Bristol Myers Squibb
	Doxycycline	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Simponi	C	Subcutaneous	50 Milligram, Qmo	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Methotrexate	C	Unknown	25 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060872	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1066248		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Norepinephrine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Alteplase			S	Intravenous (not otherwise specified)	25 Milligram Over 2 Hours		Mylan
	Alteplase			S	Intravenous (not otherwise specified)	25 Milligram Over Subsequent 22 Hours		Mylan
	Phenylephrine			S	Unknown	Unk		Mylan
	Vasopressin			S	Unknown	Unk		Mylan
	Heparin			C		10 Units/Kg/H		Mylan
	Heparin			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060877	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1066343		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Qd		Not Reported
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4 Gram 4g/6h		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	600 Milligram, Bid		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	300 Milligram, Bid		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	300 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Tid 3 Times Daily, 200mg/8h		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	2 Gram, Q8h		Mylan
	Enoxaparin			C	Subcutaneous	6000ui/L/12h		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061153	EXPEDITED (15-DAY)		OT	CA-ACCORD-191720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Lyrica			S				Not Reported
	Mirtazapine			S				Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061175	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802411		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder; Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis; Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection	Methylprednisolone Acetate			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061314	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803577		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr

Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061379	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061385	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals;	Meloxicam			S	Unknown			Teva

Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Methotrexate	S	Unknown		Barr
	Leflunomide	S	Unknown		Barr
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Unknown	80 Milligram Daily;	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Humira	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803747			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061735	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061736	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059214			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	2 Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Naproxen	S	Unknown	50 Mg, 2 Every 1 Day		Not Reported
Rituximab	S	Unknown			Not Reported
Vioxx	S	Unknown			Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Leflunomide	C	Unknown	10 Milligram		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061757	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804287		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061759	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804261		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Orencia		S	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Sulfasalazine		C	Oral	1 Gram Daily;	Not Reported
	Xeljanz		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061764	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804257		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061765	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805552		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061766	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804292			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061771	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805611			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	C	Unknown		Not Reported
	Tofacitinib	C	Oral	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805615			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061773	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Baricitinib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061868	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1066576		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Doxycycline			S	Unknown	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061948	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057795		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral			Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram, Qd		Not Reported
	Topicort [Desoximetasone]			S	Cutaneous	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062102	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1804195		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Oxycodone			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral	2 Dosage Forms Daily;		Not Reported
	Lyrica	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062108	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803712		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062182	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide		S	Unknown		Barr
	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062224	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803266		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062227	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804303		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062249	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown	Solution Subcutaneous		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062250	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804184		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate	Oxycodone			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Increased; Stomatitis; Urticaria	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062361	EXPEDITED (15-DAY)		OT	NVSC2020IT202375		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062702	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056963		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram (Cyclical)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Prednisone			S	Unknown	9 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram (Cyclical)		Not Reported

Xeljanz	S	Oral	5 Milligram, Q12h		Not Reported
Xeljanz	S	Unknown	1 Dosage Form, Qd		Not Reported
Dexamethasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062783	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Milligram Daily;		Not Reported
	Tiaprofenic Acid			C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18062913	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1803539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr

Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral	3 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18063000	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803743		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Milligram Daily;		Not Reported
	Aspirin[Acetylsalicylic Acid]			C	Unknown			Not Reported
	Aspirin[Acetylsalicylic Acid]			C	Unknown	81 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Tiaprofenic Acid			C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18063795	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803548			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18063840	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057340		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Methotrexate		S	Unknown	25 Milligram, Qwk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Unknown	1 Gram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064530	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Gabapentin			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	11580709	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1471671-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Cutaneous Lupus Erythematosus; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Glossodynia; Hand Deformity; Helicobacter Infection;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pain; Pemphigus; Pericarditis; Product Intolerance; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Skin Wound; Swelling; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Apo-Sulfasalazine	S	Oral	Enteric Coated	Not Reported
	Apo-Sulfasalazine	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Apo Prednison	S	Unknown		Not Reported
	Fosamax	S	Intracavernous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Topicort [Hydrocortisone Acetate]	S	Oral		Not Reported
	Topicort [Hydrocortisone Acetate]	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported

	Stelara	S	Unknown	Not Reported
	Hydrocortisone Acetate	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Zyrtec-D	S	Unknown	Not Reported
	Cortisone	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Atasol [Paracetamol]	C		Not Reported
	Salazopyrine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	12381245	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061262		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Mycophenolate Mofetil Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Teva Mycophenolate	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Lyrica	S	Oral	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Mycophenolate	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Pregabalin	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported

	Prednisone		C	Unknown	25 Milligram, Qd Qd, Decrease Dose Weekly	Not Reported
	Prednisone		C	Unknown	1 Dosage Form, Qd	Not Reported
	Piroxicam		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	12463903	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016074503		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Crestor			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Oral	5 Mg, Bid		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Humira	S	Subcutaneous			Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	12695500	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245898		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Vein Disorder	Enbrel			S	Subcutaneous	50 Mg		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Xeljanz			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S		2 G		Pfizer
	Actemra			S	Subcutaneous	162 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Hydroxychloroquine Sulphate			S		Unk		Not Reported
	Hydroxychloroquine Sulphate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported
	Folic Acid			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Gold			S		50 Mg, Weekly		Not Reported
	Apo-Prednisone			S		5 Mg		Not Reported
	Apo-Prednisone			S		5 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Fosamax	C		Unk		Not Reported
Ibuprofen	C		Unk		Not Reported
Lisinopril	C		Unk		Not Reported
Vit D3	C		Unk		Not Reported
Alendronate Sodium	C		Unk		Not Reported
Mtx [Methotrexate]	C		Unk		Not Reported
Fosavance	C		Unk		Not Reported
Synthroid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	13152951	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1848651-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Chest Pain; Drug Ineffective; Drug Intolerance; Epicondylitis; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Limb Fracture	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Lyophilized Powder		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Procytox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	13816338	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017217268		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Surgical Failure; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			C	Unknown	15 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	13819745	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017112611			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported

Methotrexate	S	Subcutaneous	25 Milligram		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram		Not Reported
Minocycline	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
Apo-Azathioprine	S	Unknown	100 Milligram		Not Reported
Apo-Minocycline	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	400 Milligram		Not Reported
Amoxil	C	Unknown	Unk		Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C		Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram		Not Reported
Leflunomide	C		Unk		Not Reported
Clavulanate Potassium	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	14773054	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018052058		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Stelara	S	Subcutaneous	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Otezla	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	14868417	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2018061435		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Joint Swelling; Migraine; Miliaria; Nausea; Off Label Use; Oral Pain; Pain In Extremity; Pancreatitis; Peripheral Swelling; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Sulfasalazine			S	Unknown	11:1 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	1.0 Gram, Bid		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Orencia	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Celecoxib	S	Unknown	200 Milligram, Q12h	Not Reported
Dilaudid	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Citalopram	C		10 Milligram, Qd	Not Reported
Lorazepam	C	Unknown	1 Milligram, Qhs (At Bedtime)	Not Reported
Pantoloc	C		40 Milligram, Bid	Not Reported
Pantoloc	C			Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Celebrex	C	Unknown	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	15589814	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018154303		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test	Enbrel			S	Unknown	50 Milligram		Amgen
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported

Positive	Leflunomide	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Unknown	5 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	5 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	5 Milligram	Not Reported
	Prednisone	C		Unk, Qwk, (Endocervical Route),	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	15594889	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2018154608		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Unevaluable Event; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	10 Milligram, Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Q2wk		Not Reported

Plaquenil	S	Unknown	200 Milligram, Bid		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Apo-Leflunomide	S	Oral	10 Milligram		Not Reported
Amlodipine	C	Unknown	Unk		Not Reported
Amlodipine	C		Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Arava	C		Unk		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	50 Unk		Not Reported
Naproxen	C		500 Milligram		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Prednisone	C		Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C		Unk		Not Reported
Viread	C	Unknown	Unk		Not Reported
Viread	C		Unk		Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	15738471	NON-EXPEDITED			US-PFIZER INC-2018519400		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Pennsaid			S		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	16064786	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	16081565	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1022962		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Simponi	C	Unknown		Not Reported
	Atenolol	C	Oral	50 Milligram Daily;	Not Reported
	Hydrochlorothiazide	C	Oral	25 Milligram Daily;	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	16082874	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1022849		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	200 Milligram Daily;		Actavis
	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo-Acetaminophen Tab 325mg	S	Unknown		Not Reported
	Apo-Acetaminophen Tab 325mg	S			Not Reported
	Tylenol	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen /Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Synthroid	C			Not Reported
	Xeljanz	C	Unknown		Not Reported
	Celebrex	C	Oral	400 Milligram Daily;	Not Reported
	Celebrex	C			Not Reported
	Hydromorphone Hcl	C	Unknown		Not Reported
	Celecoxib	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25 Milligram Daily;	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Tylenol W/Codeine No.3	C	Unknown		Not Reported
	Codeine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	16119643	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019128214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Naproxen	C		500 Mg, 1x/Day	Not Reported
	Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	16227030	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Methotrexate			S	Unknown	25 Dosage Form, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Q.Wk.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Sulfasalazine	S	Oral	2000 Mg, Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Celebrex	C	Oral	200 Mg, Bid		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Mg, Q.Wk.		Not Reported
Hydromorphone Hydrochloride	C	Unknown	Unk		Not Reported
Enbrel	C	Subcutaneous	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17004240	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103496		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Aleve	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Bupropion	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17153987	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027344			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported

	Zopiclone	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17369219	NON-EXPEDITED			CA-AMGEN-CANSP2016056029		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	0.8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Orencia			S	Unknown	750 Mg, Q4wk		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Mg, Q8wk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Certolizumab Pegol	C	Unknown	Unk		Not Reported
Tofacitinib	C		Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17671014	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031107		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cough; Dyspnoea; Injection Site Haemorrhage; Oropharyngeal Pain; Painful Respiration	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17765746	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported

	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17916138	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2020AMR104268		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Coombs Positive Haemolytic Anaemia; Depression; Dizziness; Drug Hypersensitivity; Fatigue; Feeling Abnormal; Haemoglobin Decreased; Headache; Hypoaesthesia; Ill-Defined Disorder; Joint Range Of Motion Decreased; Joint Warmth; Judgement Impaired; Lymphocyte Count Decreased; Mean Platelet Volume Increased; Memory	Benlysta			S	Intravenous (not otherwise specified)	625 Mg		Glaxosmithkline
	Amoxicillin			S		Unk		Glaxosmithkline
	Rituxan			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	200 Mg, Bid		Not Reported

Impairment; Muscular Weakness; Myalgia; Nervousness; Paraesthesia; Pruritus; Rash; Raynaud'S Phenomenon; Swelling; Tenderness; Tinnitus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17969637	EXPEDITED (15-DAY)		DE, HO	ES-MYLANLABS-2020M1059445		72 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S		Unk		Not Reported
	Lopinavir/Ritonavir			S		Unk		Not Reported
	Hydroxychloroquine /00072603/			S		Unk		Mylan
	Ceftriaxone			S		Unk		Mylan
	Interferon Beta-1b			S	Subcutaneous	Unk		Mylan
	Metilprednisolona /00049601/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17987303	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490324		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Unknown
	Enbrel			S	Unknown	25 Milligram, Unk		Unknown
	Enbrel			S	Unknown	25 Milligram, Bid		Unknown
	Enbrel			S	Unknown	25 Milligram, Q2wk		Unknown
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Unknown
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Unk		Pfizer
	Rituximab			S	Intravenous (not	Unk		Pfizer

		otherwise specified)		
Actemra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Unknown	15 Mg, Weekly	Not Reported
Humira	S	Unknown	40 Milligram, Q2wk	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Unk	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Unk	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q2wk	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	15 Milligram, Qwk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Unk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Intravenous (not otherwise specified)	200 Milligram, Bid		Not Reported
Sulfasalazine	C	Unknown	1 Gram, Bid		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18029238	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200715443		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18031223	EXPEDITED (15-DAY)		OT	CA-ACCORD-190370		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate	S	Unknown		Accord
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Baclofen	C	Unknown		Not Reported
	Dorzolamide/Timolol	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Levaquin	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18035612	EXPEDITED (15-DAY)		OT	CA-ACCORD-190568		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Arthritis	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Prednisone	C	Unknown	1 Every 24 Hours	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18037036	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200715882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18037114	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202007007186			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia

Sarilumab	S	Subcutaneous	200 Mg, Qow		Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Weekly		Not Reported
Olumiant	S	Oral	4 Mg, Qd		Not Reported
Dekristol	C		Unk		Not Reported
Folic Acid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18043243	EXPEDITED (15-DAY)		OT	IT-ROCHE-2643047			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate			S	Oral			Not Reported
	Roactemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Oral	5 Milligram, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18061967	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059060		89 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition	Orencia			S	Unknown			Bristol Myers Squibb

Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Anakinra	S	Unknown		Not Reported
	Arva	S	Oral	10 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	2 Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Naprosyn [Naproxen Sodium]	S	Oral	500 Milligram, Bid	Not Reported
	Rituximab	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Leflunomide	C	Unknown	10 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062132	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056601		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Lower Respiratory Tract	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Abatacept			S				Bristol Myers Squibb
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported

Infection; Malaise; Meniscus Injury; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure	Methotrexate	S	Unknown	1 Dosage Form	Not Reported
	Sulfasalazine	S	Oral	2 Gram, Qd	Not Reported
	Tramacet	S	Oral	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported
	Depo-Medrol	C	Subcutaneous	Unk, Qmo	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	1 Milligram	Not Reported
	Lyrica	C	Oral	150 Milligram	Not Reported
	Metformin	C	Unknown	5 Milligram	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
	Nortriptyline	C	Unknown	2 Dosage Form	Not Reported
	Nortriptyline	C			Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062194	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804258		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Enbrel	S	Unknown			Not Reported
Actemra	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Unknown			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Supeudol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062267	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062278	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1805549		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Enbrel		S	Unknown	Not Reported
	Etanercept		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tocilizumab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062281	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805474		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Align			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Retinal Toxicity	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Intramuscular			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sns-Asa Ec			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062315	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Levothyroxine Sodium			S	Oral	.075 Microgram Daily;		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Azathioprine			C		50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062724	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804323		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis	Leflunomide			S	Unknown			Barr

Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Vomiting	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Levaquin	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062728	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000062			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Hydroxychloroquine			S	Oral	400 Mg		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported

	Arabloc	S	Unknown	Unk		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062751	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201610-005091			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062755	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Folic Acid	C	Unknown		Not Reported
Pantoprazole Magnesium	C	Unknown		Not Reported
Tenofovir Disoproxil Fumarate	C			Not Reported
Xeljanz	C			Not Reported
Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062760	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804359		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Transaminases Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062768	EXPEDITED (15-DAY)		HO, OT	NL-ADVANZ PHARMA-202007007270			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hallucination; Hallucination, Auditory; Nocturnal Fear; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062789	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062795	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804552			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062797	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062801	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804524			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062802	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804523		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062832	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1804666		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062836	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1804635		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Atenolol	C	Oral	50 Milligram Daily;	Not Reported
	Hydrochlorothiazide	C	Oral	25 Milligram Daily;	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	300 Milligram Daily;	Not Reported
	Simponi	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062877	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1804291		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Oxycodone Hydrochloride			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Minocycline			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Sulfasalazine		S	Unknown	Not Reported
	Ilaris Single-Use Vial		C	Subcutaneous	Not Reported
	Lyrica		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062919	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective For Unapproved Indication; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Leflunomide			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062920	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804330		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062924	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804367			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062956	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804266			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported

Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown	20 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062988	EXPEDITED (15-DAY)		LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-254562		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Unknown	500 Mg/24 First Day Then Lower Dosis To 250 Mg/24		Sun
	Lopinavir (1271a)			S	Unknown	200/50 2 Tablets/12 Hours		Not Reported
	Hidroxicloroquina (2143a)			S	Unknown	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062993	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254289		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Venlafaxine			S	Unknown			Sun
	Hydroxychloroquine			S	Unknown			Ipca

Methotrexate	S	Oral	20 Milligram, Weekly		Sun
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 1 Week		Not Reported
Apo-Azathioprine	S	Unknown			Not Reported
Arava	S	Unknown			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous	40 Milligram, 1 Every 1 Weeks		Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, 1 Every 1 Months		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every One Day		Not Reported
Azathioprine	S	Unknown			Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062999	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057259		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone Acetate			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

	Folic Acid		C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063109	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2020-03756		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	600 Milligram, Bid, Every 12 Hours For 1 Day		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd, For 4 Days		Lupin
	Dobutamine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063173	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804362		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063175	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804427		63 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Leflunomide	S	Unknown		Barr
	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	100 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063184	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059444			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Zostavax	S	Subcutaneous	500 Milligram		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported
Diclofenac	C	Subcutaneous	100 Milligram		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	10 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063193	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063286	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Doxycycline Hyclate			S	Unknown			Actavis

Enbrel	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063318	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804512		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung;	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methylprednisolone Acetate		C	Other	80 Milligram Daily;	Not Reported
	Methylprednisolone Acetate		C	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063319	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804532			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063366	EXPEDITED (15-DAY)		OT	ES-GYP-000008		52 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Chorioretinitis; Macular Degeneration	Prednisone			S	Unknown			Geneyork Pharma
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063532	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02774		66 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Overdose	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (Daily Dose 7mg/Kg)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063555	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2020-03776		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	600 Milligram, Bid, For 1 Day		Lupin
	Hydroxychloroquine			S	Oral	400 Milligram, Qd, For 4 Days		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18063845	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-253845		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Lopinavir/Ritonavir			S	Unknown	400-100 Mg/12 H		Not Reported
	Ceftriaxone			S	Unknown	2 Gram, Qd		Not Reported
	Dexamethasone			S	Unknown	20 Milligram, Bid		Sun

Enoxaparin Sodium	S	Unknown	40 Milligram, Qd		Not Reported
Diazepam	S	Unknown	20 Milligram, Unk		Not Reported
Levetiracetam	S	Unknown	1500 Milligram, Unk		Sun
Lacosamide	S	Unknown	200 Milligram, Unk		Sun
Valproic Acid	S	Unknown	1000 Milligram, Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064068	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-03777		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Electrocardiogram Qt Prolonged; Hypotension; Off Label Use; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Lupin
	Dobutamine			S	Unknown	Unk		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Nitroglycerine			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064083	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059465			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Rituximab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064164	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2020-03778		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	600 Milligram, Every 12 Hours For 1 Day		Lupin
	Hydroxychloroquine			S	Oral	400 Milligram, Qd, For 4 Days		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Tacrolimus			C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064208	EXPEDITED (15-DAY)		OT	CA-ACCORD-191948		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Toxicity To Various Agents	Methotrexate			S	Unknown			Accord
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Oral	3 Every 1 Days		Not Reported
	Paracetamol			C	Unknown			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064209	EXPEDITED (15-DAY)		OT	CA-ACCORD-191946		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Etanercept			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Dexamethasone			C				Not Reported
	Desoximetasone			C				Not Reported
	Reactine			C				Not Reported
	Paracetamol			C				Not Reported
	Gabapentin			C				Not Reported
	Cetirizine			C				Not Reported
	Hydrocortisone			C				Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
	Methotrexate	S	Unknown		Accord
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064857	EXPEDITED (15-DAY)		OT	CA-ACCORD-192064			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Sulfasalazine			S				Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	1 Every 1 Days Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064859	EXPEDITED (15-DAY)		OT	CA-ACCORD-191861			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported

	Arava	S	Oral	Not Specified	Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Other	Not Specified	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064863	EXPEDITED (15-DAY)		OT	CA-ACCORD-191873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tofacitinib	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported
Rabeprazole	C	Oral	1 Every 24 Hours		Not Reported
Methotrexate	S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064865	EXPEDITED (15-DAY)		OT	CA-ACCORD-191874			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Adalimumab			S	Unknown	1 Every 2 Weeks		Not Reported
	Cimzia			S	Subcutaneous	Single Pre Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Rabeprazole			C	Oral	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064877	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Lower Respiratory Tract Infection	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Plaquenil			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cholecalciferol			C	Oral			Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen			C	Unknown			Not Reported
	Folic Acid			C	Oral	1 Milligram Daily;		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Pilocarpine Hydrochloride			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	3000 Milligram Daily;		Not Reported
	Vitamins Nos			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064879	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804435		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nephrolithiasis; Somnolence; Visual Impairment	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown	50 Milligram Daily;	Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tylenol	S	Unknown		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064903	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057346			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	2 Every 1 Week		Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Oral	500 Milligram, Bid	Not Reported
	Rituximab	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064917	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804672		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Lung Neoplasm Malignant; Lung Neoplasm Malignant; Osteoarthritis; Pancytopenia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Elavil			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Lansoprazole			C	Unknown	30 Milligram Daily;		Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18064965	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Cosentyx		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065029	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline Hyclate			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065030	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804674		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065058	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804476			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pancytopenia; Rash	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Asaphen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065059	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804496		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Arthralgia; Diarrhoea	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	25 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065060	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Mg		Barr
	Mirtazapine			S	Unknown	15 Mg		Teva
	Mirtazapine			S	Unknown	15 Mg		Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065068	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Mirtazapine		S	Unknown	Teva
	Sulfasalazine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Lyrica		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065071	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frequent Bowel Movements; Rash; Retinal Toxicity; Stomatitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065075	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804297			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065079	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065083	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804516		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr

Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
Otezla	S	Unknown	60 Milligram Daily;		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Prednisone	C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065117	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1804489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	25 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	50 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	25 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Indocid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Oral		Not Reported
	Cymbalta		C	Oral	30 Milligram Daily;	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065120	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065122	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065123	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1804248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065132	EXPEDITED (15-DAY)		OT	PR-ADVANZ PHARMA-202007007326			Unknown	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticipatory Anxiety; Anxiety; Blood Glucose Increased; Depression; Incorrect Dose Administered; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Humira 40mg/0.8ml			S	Subcutaneous	40 Mg (40 Mg,1 In 14 D)		Not Reported
	Medrol			S	Oral	Unk		Not Reported
	Medrol			S				Not Reported
	Synthyroid			C	Oral			Not Reported
	Restoril			C	Oral	30 Mg		Not Reported
	Restoril			C				Not Reported
	Klonopin			C	Oral	2.5 Mg		Not Reported
	Klonopin			C				Not Reported
	Atenolol			C	Oral	25 Mg		Not Reported
	Amaryl			C	Oral	Unk		Not Reported
	Methotrexate			C	Oral	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065143	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804368		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Aspirin [Acetylsalicylic Acid]	C			Not Reported
	Cymbalta	C			Not Reported
	Hydromorphone	C			Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065168	NON-EXPEDITED			US-ADVANZ PHARMA-202007007046			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S		200 Mg, Bid, Plaquenil		Concordia
	Methotrexate			S		15 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065187	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056981		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Orencia			S	Subcutaneous	150 Milligram, Qmo		Bristol Myers Squibb
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Naproxen			S	Unknown	500 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065205	NON-EXPEDITED			US-ADVANZ PHARMA-202007007279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Hydroxychloroquine			S		Unk		Concordia
	Arava			S		Unk		Not Reported
	Kevzara			S	Subcutaneous	200 Mg Every Other Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065224	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057351		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065236	EXPEDITED (15-DAY)		OT	CA-ACCORD-191883			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Oral			Not Reported
	Cimzia	S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Enbrel	S	Subcutaneous	2 Every 1 Days		Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine	S	Oral	2 Every 1 Days		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Every 4 Weeks		Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days		Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral	2 Every 1 Days		Not Reported
	Methotrexate	S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065237	EXPEDITED (15-DAY)		OT	CA-ACCORD-191881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065243	EXPEDITED (15-DAY)		HO	CA-ACCORD-191928		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate	S	Oral		Accord
	Actemra	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	2 Every 1 Days	Not Reported
	Arava	C	Oral		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065247	EXPEDITED (15-DAY)		OT	US-ROCHE-2645340			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bk Virus Infection; Dyspnoea; Febrile Neutropenia; Hyperglycaemia; Hyperphosphataemia; Hyponatraemia; Hypophosphataemia; Hypotension; Hypothyroidism; Influenza; Rheumatoid Arthritis; Upper Respiratory Tract Infection	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S			Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S			Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S			Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported
	Fludarabine Phosphate	S	Unknown		Not Reported
	Fludarabine Phosphate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065248	EXPEDITED (15-DAY)		OT	CA-ACCORD-191878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065250	EXPEDITED (15-DAY)		OT	CA-ACCORD-191875			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate	S	Oral	1 Every 2 Weeks		Accord
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Cimzia	S	Subcutaneous	Single Pre Filled Syringe		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S		2 Every 1 Days		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Orencia	C	Unknown			Not Reported
	Tofacitinib	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065252	EXPEDITED (15-DAY)		OT	CA-ACCORD-192058		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol			C	Oral			Not Reported
	Xeljanz			C	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065253	EXPEDITED (15-DAY)		OT	CA-ACCORD-192060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate	S	Unknown	1 Every 1 Weeks		Accord
	Sulfasalazine	S	Unknown	1 Every 24 Hours		Not Reported
	Enbrel	S	Unknown			Not Reported
	Actemra	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Oral	1 Every 24 Hours		Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 24 Hours		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065266	EXPEDITED (15-DAY)		OT	CA-ACCORD-191953		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Deformity; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Pneumococcal Vaccine			C	Intramuscular			Not Reported
	Xeljanz			C	Oral	1 Every 12 Hours		Not Reported
	Methotrexate			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065353	EXPEDITED (15-DAY)		HO	CA-ACCORD-191973		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug	Methotrexate			S	Subcutaneous	1 Every 2 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Anakinra			S	Intravenous (not otherwise specified)	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 1 Days		Not Reported

Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine	S	Oral	1 Every 1 Days		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Every 1 Weeks; 5 Mg		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Prednisone	S	Oral	2 Every 1 Days; 1.3 Mg And 3 Mg		Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days		Not Reported
	Triamcinolone	S	Intravenous (not otherwise specified)	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065364	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057957		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; C-Reactive Protein Increased; Condition Aggravated; Gastritis; Gravitational Oedema; Hypertension; Loss Of Personal Independence In Daily Activities; Musculoskeletal Chest Pain; Oesophagitis; Pain; Palpitations; Spinal Pain	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Xeljanz			S	Unknown			Not Reported
	Simponi			S				Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown	200 Milligram, Qd		Not Reported
	Celebrex			S	Unknown	200 Milligram, Bid, Prn		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Elavil [Allopurinol]			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported
	Multivitamin [Vitamins Nos]			C	Unknown	Unk		Not Reported
	Vit D			C	Unknown	Unk		Not Reported
	Indapamide			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported

	Tiazac [Diltiazem Hydrochloride]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065410	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-03519		69 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (Loading Dose)		Lupin
	Azithromycin			S	Oral	500 Milligram, Qd		Lupin
	Azithromycin			S	Oral	250 Milligram, Qd		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	80 Milligram, Bid		Lupin
	Methylprednisolone			S				Lupin
	Meropenem			C	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported
	Cefuroxime Axetil			C	Unknown	Unk		Not Reported
	Linezolid			C	Intravenous (not otherwise specified)	600 Milligram, Bid		Not Reported
	Favipiravir			C	Oral	1600 Milligram, Bid		Not Reported
	Favipiravir			C	Oral	600 Milligram, Bid (Maintenance Dose)		Not Reported
	Enoxaparin			C	Subcutaneous	0.6 Milliliter, Qd		Not Reported
	Acetylcysteine			C	Intravenous (not otherwise specified)	300 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065499	EXPEDITED (15-DAY)		OT	NVSC2020IT201653			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes	Rosuvastatin Calcium			S	Oral	10 Mg, Qd (5 Milligram, Bid)		Novartis

Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate	S	Oral			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Xeljanz	C	Oral	10 Mg, Qd (5 Milligram, Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065572	EXPEDITED (15-DAY)		OT	CA-ACCORD-191912		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastrointestinal Disorder; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065575	EXPEDITED (15-DAY)		OT	US-ACCORD-191639		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Hydroxychloroquine			S				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065588	EXPEDITED (15-DAY)		OT	CA-ACCORD-191913		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Intravenous (not otherwise specified)			Accord
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Lantus			C	Subcutaneous	Solution Subcutaneous		Not Reported
	Lozide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065646	EXPEDITED (15-DAY)		HO, OT	NVSC2020US205924		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065879	EXPEDITED (15-DAY)		HO	IE-MYLANLABS-2020M1066972		22 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Off Label Use	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065906	EXPEDITED (15-DAY)		HO, OT	BH-LUPIN PHARMACEUTICALS INC.-2020-03614		54 YR	Male	BHR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Ceftriaxone Injection			S	Unknown	Unk		Lupin
	Piperacilline/Tazobactam			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	400 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065907	EXPEDITED (15-DAY)		HO, OT	BH-LUPIN PHARMACEUTICALS INC.-2020-03567		95 YR	Male	BHR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Haematuria; Off Label Use; Renal Impairment	Hydroxychloroquine Sulfate Tablets			S	Unknown	200 Milligram, Bid		Lupin
	Lopinavir/Ritonavir			S	Unknown	Unk Unk, Qd		Not Reported
	Piperacilline/Tazobactam			S	Unknown	Unk Unk, Qid		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram, Single (Half-An-Hour Duration)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065919	EXPEDITED (15-DAY)		HO, OT	BH-LUPIN PHARMACEUTICALS INC.-2020-03615		64 YR	Male	BHR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ribavirin			S	Unknown	Unk		Not Reported
	Piperacilline/Tazobactam			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	400 Milligram 2 Doses		Not Reported
	Pegylated Interferon Alfa-2a			S	Unknown	Unk Unk, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065972	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1067326		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Hypoxia; Off Label Use; Respiratory Distress; Respiratory Failure	Dexamethasone			S	Unknown	Kpd Regimen		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Carfilzomib			S	Unknown	Kpd Regimen		Mylan
	Pomalidomide			S	Unknown	Kpd Regimen		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066128	EXPEDITED (15-DAY)		HO, OT	BH-LUPIN PHARMACEUTICALS INC.-2020-03616		37 YR	Male	BHR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin

	Ribavirin	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	400 Milligram, Two Doses	Not Reported
	Lopinavir/Ritonavir	S	Unknown	Unk	Not Reported
	Pegylated Interferon Alfa-2a	S	Unknown	Unk, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066452	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1067300		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066528	EXPEDITED (15-DAY)		HO	DE-ELI_LILLY_AND_COMPANY-DE202007007521		50 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Olumiant			S	Oral	4 Mg, Qd		Eli Lilly And Co
	Quensyl			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Sarilumab			S	Subcutaneous	Unk, Unknown		Not Reported
	Folic Acid			C	Oral	51 Mg, Qw		Not Reported
	Dekristol			C	Oral	2000 Iu, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066661	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2020M1066076		52 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Product Use In Unapproved Indication	Azithromycin			S	Unknown	500 Mg(On The First Day)		Not Reported
	Azithromycin			S	Unknown	250 Mg(Daily On The Following 4 Days)		Not Reported

	Hydroxychloroquine		S	Unknown	400 Mg(Twice A Day In First Day)	Mylan
	Hydroxychloroquine		S	Unknown	200 Mg(Twice A Day On Next 7 Days)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066716	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059526			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067014	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007328			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous	Hydroxychloroquine			S		Unk		Concordia
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067048	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001775			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	Unk		Concordia
	Enbrel	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Cosentyx	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Stelara	S	Unknown	Unk		Not Reported
	Cimzia	S	Unknown	Unk		Not Reported
	Otezla	S	Oral	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Leflunomide	C		Unk		Not Reported
	Methotrexate	C				Not Reported
	Arava	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067102	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166495			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatitis	Hydroxychloroquine			S	Oral	200 Mg,Qd		Sanofi
	Arava			S	Oral	10 Mg,Qd		Sanofi
	Methotrexate Sodium			C		25 G, Qw		Not Reported
	Humira			C				Not Reported
	Cimzia			C				Not Reported
	Orencia			C				Not Reported
	Cortisone			C		Unk		Not Reported
	Iodine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067354	EXPEDITED (15-DAY)		OT	KR-BAYER-2020-147495		68 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Therapeutic Product Effective For Unapproved Indication	Interferon Beta - 1b	S	Unk	Bayer
	Hydroxychloroquine	S	Unk	Not Reported
	Lopinavir + Ritonavir	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067522	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059499		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067789	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059528		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Lyrica			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067842	EXPEDITED (15-DAY)		OT	NVSC2020MY205179		35 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus; Tuberculosis	Azathioprine			S	Unknown	125 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	0.75 Mg/Kg		Not Reported
	Prednisolone			S	Oral	1 Mg/Kg		Not Reported
	Prednisolone			S	Oral	0.5 Mg/Kg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

	Methylprednisolone	S	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	0.5 G/M2 (850 Mg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057306		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Orencia			S	Subcutaneous	150 Milligram, Qmo		Bristol Myers Squibb
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unknown Dose, Frequency Every One Week		Not Reported
	Naproxen			S	Unknown	500 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18067883	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1066160		49 YR	Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Nausea; Off Label Use; Transaminases Increased; Vomiting	Lopinavir/Ritonavir			S	Oral	2 Cp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 12/12h Em D0		Mylan
	Plaquinol			S		Unk		Mylan
	Trazodone			C	Oral	100 Milligram, Qd		Mylan

Trazodone	C		Unk	Mylan
Furosemide	C		10 Milligram, Total	Mylan
Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Mylan
Metoclopramide	C		10 Mg Sos (23-03 A 25-03); 10 Mg 3xdia (25-03 A 27-03)10 Mg Sos (27-03 A 04-02)	Mylan
Metoclopramide	C		10 Mg Sos (23-03 A 25-03); 10 Mg 3xdia (25-03 A 27-03)10 Mg Sos (27-03 A 04-02)	Mylan
Metoclopramide	C		10 Mg Sos (23-03 A 25-03); 10 Mg 3xdia (25-03 A 27-03)10 Mg Sos (27-03 A 04-02)	Mylan
Ceftriaxone	C	Intravenous (not otherwise specified)	2000 Milligram, Qd	Mylan
Metamizole Magnesium	C	Oral	575 Milligram, Prn	Mylan
Monopotassium Phosphate	C	Intravenous (not otherwise specified)	20 Milliliter, Qd	Mylan
Ondansetron	C		8 Milligram, Prn	Mylan
Ondansetron	C		Unk	Mylan
Levothyroxine Sodium	C	Oral	75000 Nanogram, Qd	Mylan
Levothyroxine Sodium	C		Unk	Mylan
Paracetamol	C	Oral	1000 Milligram, Prn	Mylan
Paracetamol	C		Unk	Mylan
Oxazepam	C	Oral	15 Milligram, Prn	Mylan
Oxazepam	C		Unk	Mylan
Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Mylan
Escitalopram	C	Oral	10 Mg 1xdia (Até 25-03) E 20 Mg (02-04)	Mylan

	Cloreto De Potassio		C	Intravenous (not otherwise specified)	Unk	Mylan
	Zofran /00955302/		C	Oral	15 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18068074	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059136		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Orencia			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18068600	EXPEDITED (15-DAY)		DE	NVSC2020IT208624		67 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Product Use In Unapproved Indication; Pyrexia; Respiratory Gas Exchange Disorder	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Methylprednisolone			S	Unknown	80 Mg		Not Reported
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	2 Doses		Not Reported
	Enoxaparin			C	Unknown	50 Iu/Kg, Qd		Not Reported
	Sodium Heparin			C	Intravenous (not	1000 Iu/H		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18068691	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2020278264		52 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Product Use In Unapproved Indication	Azithromycin			S		500 Mg(On The First Day)		Pfizer
	Azithromycin			S		250 Mg(Daily On The Following 4 Days)		Pfizer
	Hydroxychloroquine			S		400 Mg(Twice A Day In First Day)		Not Reported
	Hydroxychloroquine			S		200 Mg(Twice A Day On Next 7 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	11962064	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2012074066		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	C	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
	Leflunomide	C	Unknown	Unk Unk, Bid	Not Reported
	Leflunomide	C	Oral	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Hcq	C		Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	13549390	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017071781		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Mg, As Necessary		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	14156463	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017163488		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068330	EXPEDITED (15-DAY)		OT	CA-ACCORD-192066		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S				Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 6 Weeks		Not Reported
	Orencia			S				Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Enbrel			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S				Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068332	EXPEDITED (15-DAY)		OT	CA-ACCORD-192068		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Methotrexate			S	Unknown	Not Specified		Accord
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068413	EXPEDITED (15-DAY)		OT	CA-ACCORD-192071			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated;	Methotrexate			S				Accord
	Actemra			S				Not Reported

Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Apo-Leflunomide	S				Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine	S				Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Meloxicam	C				Not Reported
	Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068552	EXPEDITED (15-DAY)		OT	CA-ACCORD-192171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Methotrexate			S				Accord
	Cosentyx			S				Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068554	EXPEDITED (15-DAY)		OT	CA-ACCORD-192266		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell	Methotrexate			S	Oral	1 Every 1 Weeks, Not Specified		Accord
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported

Sedimentation Rate
Abnormal; Restless Legs
Syndrome; Treatment
Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068560	EXPEDITED (15-DAY)		OT	CA-ACCORD-192105			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068562	EXPEDITED (15-DAY)		OT	CA-ACCORD-192108		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068566	EXPEDITED (15-DAY)		OT	CA-ACCORD-192201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous, Frequency: 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			C				Not Reported
	Gabapentin			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068576	EXPEDITED (15-DAY)		OT	CA-ACCORD-192203			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus	Methotrexate			S				Accord
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous bolus			Not Reported
	Reactine [Cetirizine]			S				Not Reported
	Pseudoephedrine			S				Not Reported
	Prednisone			S				Not Reported
	Plaquenil			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported

Erythematosus	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Fosamax	S		Not Reported
	Folic Acid	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Diclofenac	S		Not Reported
	Cortisone	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cetirizine	S		Not Reported
	Arava	S		Not Reported
	Prednisone	S		Not Reported
	Actemra	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068693	EXPEDITED (15-DAY)		OT	CA-ACCORD-192191		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Pain; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Methotrexate			S				Accord
	Codeine			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium/Rocuronium Bromide			S				Not Reported

	Rocuronium	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfamethoxazole/Trimethoprim	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068694	EXPEDITED (15-DAY)		HO, LT	CA-ACCORD-192193		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Not Specified		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Not Specified		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

Sulfasalazine	S	Unknown		Not Reported
Methotrexate	S	Intra-arterial		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068696	EXPEDITED (15-DAY)		OT	CA-ACCORD-192192		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Prednisone			S	Unknown	Not Specified		Not Reported
	Sulfasalazine			S	Unknown	Not Specified, 2 Every 1 Days		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Naproxen			C	Unknown	Not Specified, 1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown	Not Specified		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068699	EXPEDITED (15-DAY)		OT	CA-ACCORD-192194		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Lung Neoplasm Malignant; Osteoarthritis; Pancytopenia	Methotrexate	S	Unknown		Accord
	Cimzia	S	Unknown	Solution Subcutaneous Single-Use	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Elavil	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Lansoprazole	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068754	EXPEDITED (15-DAY)		OT	CA-ACCORD-192197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068756	EXPEDITED (15-DAY)		OT	CA-ACCORD-192220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord

Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068757	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-192221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate			S	Oral			Accord
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068978	EXPEDITED (15-DAY)		OT	CA-ACCORD-192204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S				Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S				Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18068979	EXPEDITED (15-DAY)		DE, HO	CA-ACCORD-192183		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bacteraemia; Body Temperature Increased; Central Nervous System Infection; Clostridium Difficile Infection; Confusional State; Decreased Appetite; Depressed Level Of Consciousness; Diarrhoea; Escherichia Infection; Headache; Nausea; Nervous System Disorder; Seizure; Somnolence; Stress Ulcer; Strongyloidiasis; Thrombosis; Upper Gastrointestinal Haemorrhage; Vomiting; Weight Decreased	Methotrexate			S	Unknown			Accord
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18069089	EXPEDITED (15-DAY)		HO	CA-ACCORD-191271		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium/Alendronic Acid			S	Unknown			Accord
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Solution Intramuscular		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18069094	EXPEDITED (15-DAY)		OT	CA-ACCORD-192111		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			C				Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate			C				Not Reported
	Prednisone			C		Frequency: 1 Every 24 Hours		Not Reported
	Xeljanz			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Cannabis Sativa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18069099	EXPEDITED (15-DAY)		OT	CA-ACCORD-191887			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Methotrexate			S				Accord
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S		Dosage Form: Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18069102	EXPEDITED (15-DAY)		OT	CA-ACCORD-192113			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	Frequency: 2 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral	Frequency: 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18069203	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2020027429			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine			S	Unknown	225 Milligram, Qd, Every 24 Hour		Macleods
	Azithromycin 250 Mg			S	Unknown	250 Milligram, Qd, Every 24 Hour		Not Reported
	Lopinavir/Ritonavir			S	Unknown	Lopinavir 400 Mg/Ritonavir 100 Mg, Every 12 Hour, Bid		Macleods
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd, Every 24 Hour		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	16003920	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2019-CA-1017774		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Minocycline			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ilaris Single-Use Vial	S	Unknown		Not Reported
Ilaris Single-Use Vial	S	Subcutaneous		Not Reported
Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)		Not Reported
Ilaris Single-Use Vial	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S			Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Marijuana	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Rituximab/Urelumab	C	Unknown		Not Reported
	Kineret	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Lyrica	C			Not Reported
	Prednisone	C	Unknown	7 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18040882	EXPEDITED (15-DAY)		CA, OT	NVSC2020IL200241			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Ecchymosis; Foetal Exposure During Pregnancy; Jaundice; Neonatal Respiratory Distress Syndrome; Oedema; Patent Ductus Arteriosus; Premature Baby; Thrombocytopenia	Prednisone			S	Transplacental	Unk (Maternal Dose 10 Mg Qd)		Novartis
	Etanercept			S	Transplacental	Unk (Maternal Dose 25 Mg)		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk (Maternal Dose 200 Mg Qd)		Not Reported
	Ampicilline (Ampicillin Sodium)			S	Transplacental	Unk (Maternal Dose: Unknown)		Not Reported
	Gentamicin			S	Transplacental	Unk (Maternal Dose: Unknown)		Not Reported
	Vancomycin			S	Transplacental	Unk (Maternal Dose: Unknown)		Not Reported

	Enoxaparin	S	Transplacental	Unk (Maternal Dose: Unknown)	Not Reported
	Metotrexat	C	Transplacental	Unk (Maternal Dose:5,Unk Q3w)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18058731	EXPEDITED (15-DAY)		HO, OT	NVSC2020FR205231		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Syncope	Sotalol			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	500 Mg, Once/Single (500 Milligram, Single)		Novartis
	Azithromycin			S	Oral	250 Mg, Qd (250 Milligram, Qd)		Novartis
	Hydroxychloroquine			S	Oral	600 Mg, Qd (200 Milligram, Tid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804286		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069540	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide			S	Oral	3.871 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069541	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069543	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804440		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069546	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804537		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069553	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804632		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Tramacet			S	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1 Milligram Daily;		Not Reported
	Lyrica			C	Oral	300 Milligram Daily;		Not Reported
	Metformin			C	Unknown	5 Milligram Daily;		Not Reported
	Metformin			C	Unknown	1000 Milligram Daily;		Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Intramuscular			Not Reported
	Methylprednisolone Acetate			C	Subcutaneous			Not Reported
	Nortriptyline			C	Unknown			Not Reported

Nortriptyline	C	Unknown			Not Reported
Nortriptyline	C	Unknown	20 Milligram Daily;		Not Reported
Risedronate Sodium	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Vagifem	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069554	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804528			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069555	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Kevzara	S	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Oral	3 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069556	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804247		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Baclofen			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Levaquin			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069557	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1804525		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804515		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804355		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral	12.5 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069563	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804244			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Kevzara	S	Unknown			Not Reported
Methotrexate	S	Oral			Not Reported
Orencia	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tofacitinib	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram Daily;		Not Reported
Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069564	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804429			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Arava			C	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069565	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069568	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804240		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis; Contraindicated Product Administered; Diverticulitis; Drug	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Syringe					
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral	100 Milligram Daily;		Not Reported
	Baclofen	C	Unknown			Not Reported
	Calcium	C	Unknown	500 Milligram Daily;		Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Estradiol	C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide	C	Unknown	40 Milligram Daily;		Not Reported
	Gravol	C	Unknown			Not Reported
	Levaquin	C	Unknown			Not Reported
	Morphine	C	Unknown			Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan	C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan	C	Ophthalmic	50 Milligram Daily;		Not Reported
	Zingiber Officinale	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069571	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Retinal Toxicity	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Aspirin Coated			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069575	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1804772			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Oral			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris Single-Use Vial			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069580	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804677		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	1 Gram Daily;		Not Reported
	Sodium Aurothiomalate			S	Parenteral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown	15 Milligram Daily;		Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804646		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Intolerance; Headache; Rheumatoid Arthritis; Tremor	Adalimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069582	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804664			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069584	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804753			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804771		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069587	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1804701			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Indication; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069697	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254818			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death Neonatal; Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Sun
	Fentanyl			S	Transplacental	Unk		Not Reported
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Midazolam			S	Transplacental	Unk		Sun
	Noradrenaline			S	Transplacental	Unk		Not Reported
	Oseltamivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18069702	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254244		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Psychotic Disorder; Self-Medication	Escitalopram			S	Unknown	10 Milligram, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	12164789	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016118471		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Enbrel			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, 2x/Day (Bid)		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S		Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)	Unk		Not Reported

Leflunomide	S	Oral	Unk		Not Reported
Apo-Leflunomide	S		Unk		Not Reported
Apo-Leflunomide	S		Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Voltaren [Diclofenac]	C		100 Mg, 1x/Day		Not Reported
Cortisone	C		10 Mg, Daily		Not Reported
Desoximetasone	C	Oral	10 Mg, 1x/Day		Not Reported
Desoximetasone	C		10 Mg, 1x/Day		Not Reported
Desoximetasone	C	Oral	5 Mg, 2x/Day		Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported
Diclofenac	C		100 Mg, 1x/Day		Not Reported
Diclofenac	C	Oral	100 Mg, Unk		Not Reported
Diclofenac	C	Oral	5 Mg, 2x/Day		Not Reported
Diclofenac	C		100 Mg, Unk		Not Reported
Diclofenac	C	Subcutaneous	100 Mg, Unk		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Cortisone	C	Subcutaneous	Unk		Not Reported
Cortisone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	12335415	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055292		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability;	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Fosamax	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Vit D3	C	Unknown	Unk	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Mtx [Methotrexate]	C		Unk	Not Reported
	Fosavance	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	12377399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016252940		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Teva Mycophenolate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
Humira	S	Unknown	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Mycophenolate	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Piroxicam	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	25 Mg, Qd, Decrease Dose Weekly	Not Reported
Prednisone	C	Unknown	1 Dosage Form, Qd	Not Reported
Methotrexate	C		Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	12405572	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016063959		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Plaquenil	S	Oral	Unk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram, Q4wk	Not Reported
	Methotrexate	S	Parenteral	22.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	22.5 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk Unk, Qwk (For 20 Weeks)	Not Reported
	Gold	S	Unknown	Unk Unk, Qd (One Every One Day)	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported

Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	22.5 Mg, Qwk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk Unk, Qwk	Not Reported
Prednisone	C	Unknown	6 Milligram, Bid	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk, Unk, Qd (One Every One Day)	Not Reported
D-Penicillamine	C		Unk	Not Reported
Minocycline	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
Prednisolone	C		6 Milligram, Qd	Not Reported
Prednisolone	C		Unk	Not Reported
Prednisolone	C		6 Milligram, Bid (One Every 12 Hours)	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Penicillamine	C	Unknown	Unk	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Phenylbutazone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	12609531	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016362505		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Therapeutic Product Effect Incomplete; Treatment Failure; Treatment Failure	Methotrexate Sodium	S	Subcutaneous	20 Mg, 1x/Day	Pfizer
	Celebrex	S		Unk	Pfizer
	Sulfasalazine	S	Oral	500 Mg	Pfizer
	Actemra	S		Unk	Not Reported
	Arava	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Risedronate Sodium	S		5 Mg	Not Reported
	Prednisolone	S		Unk	Not Reported
	Prednisolone	S		5 Mg, 1x/Day	Not Reported
	Cortisone	C		5 Mg, 1x/Day	Not Reported
	Cyclobenzaprine	C		10 Mg, As Needed (Half A Tablet)	Not Reported
	Cyclobenzaprine	C	Unknown	10 Mg, Unk	Not Reported
	Desoximetasone	C		5 Mg, 1x/Day	Not Reported
	Desoximetasone	C		5 Mg	Not Reported
	Prednisone	C		5 Mg, 1x/Day	Not Reported
	Tylenol	C		Unk, As Needed	Not Reported
	Tylenol	C		Unk	Not Reported
	Hydroxychloroquine Sulfate	C		Unk	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported
	Leflunomide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	12611441	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016366150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Cyclic		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, 2x/Week		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	13066184	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016294889		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Weekly (50 Milligram, Qwk)		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Rosuvastatin Calcium			S	Oral	5 Mg, 2x/Day (5 Mg, Bid)		Not Reported
	Rosuvastatin Calcium			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

	Azathioprine	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	13408209	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-028353		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Triatec [Codeine Phosphate;Paracetamol]			C	Unknown	Unk		Not Reported
	Atasol [Paracetamol]			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	650 Milligram, Bid		Not Reported
	Atacand			C	Unknown	Unk		Not Reported
	Hydrodiuril			C	Unknown	Unk		Not Reported
	Vitamin D [Ergocalciferol]			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Neurontin			C	Unknown	600 Milligram, Tid		Not Reported

Acetaminophen	C	Unknown	650 Milligram, Bid		Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown			Not Reported
Aluminium Acetate;Benzethonium Chloride	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Benzethonium Chloride	C	Unknown			Not Reported
Aluminum Acetate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	13825062	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017332564			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Minocycline			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported

[Hydroxychloroquine Sulfate]					
Amoxil	C	Unknown	Unk		Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C		Unk		Not Reported
Hydroxychloroquine Sulfate	C		Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram		Not Reported
Leflunomide	C		Unk		Not Reported
Adalimumab	C		Unk		Not Reported
Bcg Vaccine	C		Unk		Not Reported
Clavulin [Amoxicillin Trihydrate;Clavulanate Potassium]	C		Unk		Not Reported
Clavulanate Potassium	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	14217957	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Milligram, Q.Wk.		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk. (Duration:944)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Milligram, Q.Wk.		Not Reported

Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate Sodium		S	Subcutaneous	15 Milligram, Q.Wk.	Not Reported
	Methotrexate Sodium		S	Subcutaneous	10 Milligram, Q.Wk.	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk (Duration: 366)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Tocilizumab		S	Unknown	680 Mg, One Every 4 Weeks	Not Reported
	Tocilizumab		S	Unknown	360 Mg, Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Actemra		S	Unknown	360 Mg, Q.M.T.	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	10 Mg, Qd	Not Reported
	Ciclosporin		C	Unknown	150 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	15563291	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245089		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Off Label Use; Product Use Issue; Synovitis;	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Therapeutic Response Decreased			otherwise specified)		
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Unk	Not Reported
	Hydrochlorothiazid	C		Unk	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Sumatriptan Succinate	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Sumatriptan	C		Unk	Not Reported

	Tofacitinib			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	15575467	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016303303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Humira			S		Unk, Cyclic		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S		40 Mg, 2x/Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not	1000 Mg		Not Reported

			otherwise specified)		
	Rituxan	S		1000 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Apo-Leflunomide	S		20 Mg	Not Reported
	Leflunomide	S		20 Mg	Not Reported
	Meloxicam	C	Oral	7.5 Mg, As Needed	Not Reported
	Meloxicam	C	Oral	7.5 Mg, Unk	Not Reported
	Meloxicam	C		7.5 Mg	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisolone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	15579383	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018447943		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Cefazolin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	10 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Bid		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Mg	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Amlodipine	C		Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Arava	C		Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	50 Unk	Not Reported
Naproxen	C		500 Mg, Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Viread	C	Unknown	Unk	Not Reported
Viread	C		Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported
Xeljanz	C	Oral	5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	15630894	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105546		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk, 1 Every 1 Week	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naprosyn [Naproxen]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	15696246	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015057052		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, 2x/Week		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Ml, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Ml, 2x/Day		Pfizer
	Xeljanz			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral	10 Ml		Pfizer
	Xeljanz			S	Oral	5 Ml		Pfizer

Celebrex	S	Oral	Unk	Pfizer
Celebrex	S		Unk	Pfizer
Methotrexate Sodium	S	Unknown	Unk	Pfizer
Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Unknown	20 Mg	Pfizer
Methotrexate Sodium	S	Unknown	200 Mg, Weekly	Pfizer
Vioxx	S	Oral	Unk	Not Reported
Vioxx	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Abbott
Humira	S	Unknown	Unk	Abbott
Humira	S	Subcutaneous	40 Mg, Cyclic	Abbott
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2x/Day	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 2x/Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram (Q6wk)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported
Wellbutrin	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	15964313	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013829		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	16142580	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027232		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Orencia			S	Unknown	Unk Unk, Qmo		Bristol Myers Squibb
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported
	Minocycline			S	Unknown			Not Reported

Minocycline Hydrochloride	S	Unknown	50 Milligram	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Leflunomide	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Humira	S	Subcutaneous	400 Milligram	Not Reported
Humira	S	Unknown	40 Milligram, Q2wk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Azathioprine	S	Unknown	100 Milligram	Not Reported
Apo-Azathioprine	S	Unknown	100 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	5 Nanogram, Bid	Not Reported
Arava	S	Oral	20 Milligram, Qwk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Minocycline	S	Unknown	50 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	C	Unknown		Not Reported
Amoxicillin And Clavulanate Potassium [Amoxicillin Trihydrate;Clavulan	C	Unknown		Not Reported
Amoxil [Amoxicillin]	C	Unknown		Not Reported
Arava	C	Oral	20 Milligram, Qwk	Not Reported
Bcg	C	Intravenous (not otherwise specified)		Not Reported
Gold	C	Unknown		Not Reported
Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
Amoxicillin Trihydrate	C	Unknown		Not Reported
Amoxicillin Trihydrate And	C	Unknown		Not Reported

Clavulanate Potassium					
Hydroxychloroquine Sulfate	C	Oral	400 Milligram		Not Reported
Hydroxychloroquine	C	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	100 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram		Not Reported
Leflunomide	C	Unknown			Not Reported
Bcg	C	Intravesical	Unk		Not Reported
Amoxicillin	C	Unknown			Not Reported
Clavulin [Amoxicillin Trihydrate;Clavulanate Potassium]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	16354698	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016190551		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Naproxen			C		500 Mg, 2x/Day		Not Reported
	Viread			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	16471566	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017312936		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	25 Mg		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S		300 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S		300 Mg		Not Reported
	Rituxan			S		1000 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Rituximab			S		1000 Mg		Not Reported
	Gold			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Desoximetasone			C		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	16682231	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086774		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Sulfasalazine	C	Unknown	2 Gram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Hydroxychloroquine	C		400 Milligram Daily;	Not Reported
	Methotrexate Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	16683284	EXPEDITED (15-DAY)		OT	CA-SAOL THERAPEUTICS-2019SAO00311		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Winrho Sdf			S				Saol Therapeutics
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, 1x/Month		Not Reported
	Enbrel			S	Subcutaneous	50.0 Mg, 1x/Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, 2x/Week		Not Reported
	Humira			S	Subcutaneous	40 Mg; 1x/2weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	15 Mg, 1x/Week		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib Citrate			S	Subcutaneous	5 Mg, 2x/Week		Not Reported
	Tofacitinib Citrate			S		5 Mg, 2x/Day		Not Reported
	Benzalkonium Chloride			S				Not Reported
	Boric Acid			S				Not Reported
	Disodium Edetate			S				Not Reported
	Gold			S				Not Reported
	Celebrex			C	Oral	400 Mg		Not Reported

	Ibuprofen	C	Oral	400 Mg	Not Reported
	Lipitor	C	Oral	10 Mg, 1x/Week	Not Reported
	Lipitor	C		10 Mg, 1x/Day	Not Reported
	Prednisone	C		15 Mg, 1x/Week	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Phenylephrine Hcl	S			Not Reported
	Sodium Borate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	16683285	EXPEDITED (15-DAY)		HO	CA-SAOL THERAPEUTICS-2019SAO00307		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Varicella Zoster Immune Globulin			S	Intramuscular			Saol Therapeutics
	Actemra			S				Not Reported
	Arava			S		20 Mg, 1x/Day; 1 Every 24 Hours		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day; 1 Every 24 Hours		Not Reported
	Isoniazid			S				Not Reported
	Methotrexate			S	Subcutaneous	Unk, 1x/Week		Not Reported
	Myochrysine			S	Intramuscular	50.0 Mg, 1x/Week		Not Reported
	Plaquenil			S	Oral	200.0 Mg, 1x/Day; 1 Every 24 Hours		Not Reported
	Remicade			S	Unknown	200 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200.0 Mg; Powder For Solution Intravenous [Route: Intravenous (Not Otherwise Specified)]"		Not Reported
	Sulfasalazine			S	Oral	2000.0 Mg, 1x/Day		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17147710	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2019205773		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Prescribed; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Papilloedema; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Sulfasalazin			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown			Not Reported
	Celebrex			C		Unk		Not Reported
	Plaquenil Sulfate			C	Oral	200 Milligram, Bid		Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	400 Milligram, Qd		Not Reported

Hydroxychloroquine Sulfate	C	Subcutaneous	40 Milligram		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported
Methotrexate	C	Unknown	20 Milligram, Qwk		Not Reported
Methotrexate	C	Oral	Unk		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram		Not Reported
Methotrexate	C	Unknown	15 Milligram		Not Reported
Methotrexate	C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17255036	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-000256		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Leflunomide			S	Unknown	1 Dosage Form, Qd		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Sulfasalazine			S	Oral	2 Gram, Qd		Not Reported
	Tramacet			S	Unknown			Not Reported

Stenosis; Treatment Failure	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported
	Lyrica	C	Oral	150 Milligram, Bid	Not Reported
	Metformin	C	Unknown	500 Milligram, Bid	Not Reported
	Metformin	C	Unknown	5 Milligram, Qd	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C			Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C			Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17282858	EXPEDITED (15-DAY)		OT	NVSC2020US008551			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Dermatitis; Gluten Sensitivity	Hydroxychloroquine Sulfate			S	Oral	2 Df, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17332504	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004133		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qwk	Not Reported
	Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd	Not Reported
	Zingiber Officinale	C	Unknown	500 Microgram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17492232	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001950			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete;	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Arava			S	Oral	Unk Unk, Weekly		Not Reported
	Arava			S	Oral	Unk Unk, Weekly		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Monthly		Not Reported
	Actemra			S	Unknown	640 Unk		Not Reported

Treatment Failure	Actemra	S	Unknown	640 Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
	Cimzia	S	Subcutaneous	Unk Single-Use Prefilled Syringe	Not Reported
	Enbrel	S		50 Mg, Weekly	Not Reported
	Enbrel	S	Unknown	50 Mg	Not Reported
	Enbrel	S	Unknown	50 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Humira	S	Unknown	400 Mg	Not Reported
	Humira	S	Unknown	40 Mg	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Certolizumab	S	Subcutaneous	200 Mg, Qow	Not Reported
	Certolizumab	S	Unknown	200 Mg,Qow	Not Reported
	Certolizumab	S	Unknown	200 Mg,	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Infliximab	S	Unknown	300 Mg, Weekly	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

Simponi	S	Unknown	Unk		Not Reported
Apo-Azathioprine	S	Unknown	Unk		Not Reported
Ciclosporin	S	Oral	Unk		Not Reported
Ciclosporin	S	Unknown	Unk		Not Reported
Imuran	S	Unknown			Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Prednisone	C		Unk		Not Reported
Piroxicam	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17665208	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145791		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Xeljanz			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Calcium/Vitamin D3			C		Unk		Not Reported
	Hydrocortisone			C		Unk, 2x/Day		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Prednisone			C		20 Mg, 1x/Day		Not Reported
	Tylenol Arthritis Pain			C		2 Df, 2x/Day		Not Reported
	Xarelto			C		Unk		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17726014	EXPEDITED (15-DAY)		OT	NVSC2020CA115075		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Diclofenac			S	Unknown	50 Mg		Novartis
	Leflunomide			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Topicort			S	Subcutaneous	Unk		Not Reported
	Topicort			S	Topical	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	4 Mg		Not Reported

Humira	S	Unknown	400 Mg	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	40 Mg	Not Reported
Arava	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Methotrexate	C	Oral	25 Mg	Not Reported
Methotrexate	C	Oral	25 Mg	Not Reported
Methotrexate	C	Oral	25 Mg, Qw	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	5 Mg, Qd	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17817547	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201709-005382			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	1 Dosage Form, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17873545	EXPEDITED (15-DAY)		HO, LT, OT	BE-ADVANZ PHARMA-202005006000			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemolysis; Off Label Use; Renal Ischaemia; Toxicity To Various Agents	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Bid (Q12h, 2x/D1 Day)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg (2x/D 4days)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk, Drug Reintroduced		Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Zanidip			C		Unk		Not Reported
	Januvia			C		Unk		Not Reported
	Metformine			C		Unk		Not Reported
	Augmentin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17925695	EXPEDITED (15-DAY)		DE	CA-APOTEX-2009AP005082		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate			S	Oral	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Metformin			S	Oral	1000 Milligram		Apotex
	Metformin			S	Unknown	500 Mg, Bid		Apotex
	Metformin			S	Unknown	1000 Mg, Unk		Apotex
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Furosemide			S	Unknown	40 Milligram, Qd		Apotex
	Atorvastatin			S	Unknown	10 Milligram, Qd		Apotex
	Omeprazole			S	Oral	20 Mg, Unk		Apotex
	Combivent			S	Unknown	Unk		Not Reported
	Lasix /00032601/			S	Unknown	40 Mg, Unk		Not Reported
	Lipitor			S	Unknown	10 Milligram, Qd		Not Reported
	Nitrazadon			S	Unknown	10 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Unknown	300 Mg, Qd		Not Reported
	Losec /00661201/			S	Oral	20 Milligram, Qd		Not Reported
	Flovent			S	Unknown	Unk		Not Reported
	Ipratropium Bromide W/Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk		Not Reported
	Tylenol /00020001/			S	Unknown	500 Milligram, Qd		Not Reported
	Atrovent			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17928465	EXPEDITED (15-DAY)		CA, OT	NVSC2020US173732			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Leflunomide		S	Transplacental	Maternal Dose: Unknown	Not Reported
	Methotrexate		S	Transplacental	Maternal Dose:Unknown	Novartis
	Indomethacin		S	Transplacental	Maternal Dose:Unknown	Not Reported
	Hydrochlorothiazide		S	Transplacental	Maternal Dose:Unknown	Not Reported
	Hydroxychloroquine		S	Transplacental	Maternal Dose: Unknown	Not Reported
	Deflazacort		S	Transplacental	Maternal Dose: Unknown	Not Reported
	Chloroquine		S	Transplacental	Maternal Dose: Unknown	Not Reported
	Dopamine		S	Transplacental	Maternal Dose:Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17930586	EXPEDITED (15-DAY)		OT	NVSC2020US173696		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy; Premature Separation Of Placenta	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17933328	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Alendronate			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Prednisone			S				Apotex

	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Methotrexate	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Topical	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetason	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Topicort [Desoximetasone]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17942482	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3456609-00		61 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury; Rash	Kaletra			S	Oral	400mg+100mg, 2xdia (12 Em 12h)		Not Reported
	Plaquinol			S	Oral			Not Reported
	Morphine			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported

	Paracetamol	C	Not Reported
	Norepinephrine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17959045	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC-2020242914		72 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Methylprednisolone Sodium Succinate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Amine [Amikacin Sulfate]			S		Unk		Not Reported
	Lopinavir/Ritonavir			S		Unk		Not Reported
	Ceftriaxone			S		Unk		Not Reported
	Tocilizumab			S		3 Df (3 Bolus)		Not Reported
	Interferon Beta-1b			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18018548	EXPEDITED (15-DAY)		HO	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-037572		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction	Apixaban			S	Oral	5 Milligram, Bid		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18027331	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-034930		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Electrocardiogram Qt	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Prolonged	Oxygen		C	Unknown	Unk	Not Reported
	Cobicistat;Darunavir;Emtricitabine;Tenofovir		C	Unknown	Unk	Not Reported
	Perindopril		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18036749	EXPEDITED (15-DAY)		DE, OT	NVSC2020ES200334		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use; Pneumonia; Renal Failure; Renal Haemorrhage	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Kaletra			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18040879	EXPEDITED (15-DAY)		CA, OT	NVSC2020IL200253			Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hypothyroidism; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azathioprine			S	Transplacental	100 Mg, Qd (Maternal Dose)		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Mg, Qd (Maternal Dose)		Novartis
	Budesonide			S	Transplacental	3 Mg, Bid Maternal Dose		Not Reported
	Prednisone			S	Transplacental	10 Mg, Qd (Maternal Dose)		Not Reported
	Mesalamine			S	Transplacental	1 G, Tid (Maternal Dose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18052329	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201707-004401			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Arava			S	Unknown	Unk		Not Reported

Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure	Gold	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	Unk Unk, Weekly	Not Reported
	Methotrexate	S	Oral	25 Mg, Qd	Not Reported
	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Enbrel	S	Unknown	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18056611	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056881		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18069775	EXPEDITED (15-DAY)		OT	CA-ACCORD-192091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Methotrexate			S		1 Every 1 Weeks		Accord
	Actemra			S	Subcutaneous			Not Reported
	Arava			S		1 Every 1 Days		Not Reported
	Enbrel			S				Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18069955	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020028047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Encephalitis; Meningitis; Synovitis; Treatment Failure; Unevaluable Event	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Once Daily (Qd)		Not Reported
	Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Enbrel			S				Not Reported

	Methotrexate	S	20 Milligram, Weekly (Qw)	Not Reported
	Sulfasalazine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18069972	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202007007330			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Skin Reaction; Suspected Counterfeit Product	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070092	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804859		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cephalexin [Cefalexin]			C	Unknown	2000 Milligram Daily;		Not Reported
	Hydroxychloroquine			C				Not Reported
	Perindopril			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070154	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058349		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Once Every Two Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Dequalinium Chloride			C	Unknown	Unk		Not Reported
	Mefenamic Acid			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	6 Milligram, Qd		Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070189	EXPEDITED (15-DAY)		OT	CA-ACCORD-192065		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral; Stomatitis; Swelling; Synovitis; Tenderness	Methotrexate	S		1 Every 1 Weeks	Accord
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Hydroxychloroquine	S			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Actemra	S			Not Reported
	Enbrel	S		2 Every 1 Weeks	Not Reported
	Orencia	S		1 Every 1 Months	Not Reported
	Synthroid	C			Not Reported
	Omnaris	C		Spray, Metered Dose	Not Reported
	Norflex	C		2 Every 1 Days	Not Reported
	Loperamide	C			Not Reported
	Furosemide	C		3 Every 1 Weeks	Not Reported
	Vagifem	C	Vaginal	Vaginal Suppository	Not Reported
	Diphenhydramine	C			Not Reported
	Dilaudid	C			Not Reported
	Desoximetasone	C	Oral		Not Reported
	Pantoprazole	C			Not Reported
	Darifenacin/Darifenacin Hydrobromide	C			Not Reported
	Arava	C			Not Reported
	Arava	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070190	EXPEDITED (15-DAY)		HO	CA-ACCORD-192063		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug	Alendronate Sodium/Alendronic Acid			S		Frequency: 1 Every 1 Weeks		Accord
	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord
	Actemra			S		Frequency: 1 Every 4 Weeks		Not Reported
	Apo-Leflunomide			S				Not Reported
	Codeine			S				Not Reported

Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Enbrel	S			Not Reported
	Humira	S		Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Myochrysine	S	Intramuscular	Frequency: 1 Every 1 Weeks Solution Intramuscular	Not Reported
	Orencia	S		Frequency: 1 Every 1 Weeks	Not Reported
	Remicade	S		Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Weeks	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S			Not Reported
	Prednisone	C			Not Reported
	Ciclosporin	C			Not Reported
	Xeljanz	C			Not Reported
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord

	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Accord
	Actemra	S		Frequency: 1 Every 4 Weeks	Not Reported
	Enbrel	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070191	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020120419			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Etanercept			S	Unknown			Amgen
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported

	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070193	EXPEDITED (15-DAY)		OT	CA-ACCORD-192087		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate			S	Oral			Accord
	Xeljanz			S		2 Every 1 Days		Not Reported
	Topicort			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Sulfasalazine			S				Not Reported
	Stelara			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sarilumab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine]			S				Not Reported
	Pseudoephedrine			S				Not Reported
	Pseudoephedrine			S				Not Reported
	Plaquenil			S	Oral	1 Every 1 Days		Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 24 Hours		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Golimumab			S				Not Reported
	Fosamax			S				Not Reported
	Folic Acid			S				Not Reported

Enbrel	S	Subcutaneous	1 Every 1 Weeks		Not Reported
Diclofenac	S				Not Reported
Desoximetasone	S	Oral			Not Reported
Cortisone	S				Not Reported
Cimzia	S	Subcutaneous			Not Reported
Cetirizine	S				Not Reported
Arava	S	Oral			Not Reported
Apo-Prednisone	S				Not Reported
Actemra	S				Not Reported
Paracetamol	S				Not Reported
Tofacitinib	C				Not Reported
Salazopyrin	C				Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C				Not Reported
Topicort	S	Other			Not Reported
Sulfasalazine	S	Oral	2 Every 1 Days		Not Reported
Orencia	S	Subcutaneous			Not Reported
Methotrexate	S				Accord
Methotrexate	S	Oral	1 Every 1 Days		Accord
Methotrexate	S		1 Every 1 Days		Accord
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine	S				Not Reported
Desoximetasone	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070325	EXPEDITED (15-DAY)		OT	CA-ACCORD-192212		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported

Ray Abnormal	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Benzylpenicillin	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days	Not Reported
	Xeljanz	C	Oral	2 Every 1 Days	Not Reported
	Tylenol	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Calcium Carbonate/Calcium Lactogluconate	C			Not Reported
	Prednisone	C	Unknown	1 Every 1 Days	Not Reported
	Plaquenil	C	Unknown		Not Reported
	Methotrexate	S	Oral	1 Every 1 Days	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070335	EXPEDITED (15-DAY)		OT	CA-ACCORD-192209		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Methotrexate			S	Oral			Accord
	Penicillin-G			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			C				Not Reported

	Prednisone	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070336	EXPEDITED (15-DAY)		OT	CA-ACCORD-192213		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Acetylsalicylic Acid			C	Unknown	Not Specified, 1 Every 1 Days		Not Reported
	Tiaprofenic Acid			C	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			C	Unknown	Not Specified		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	1 Every 1 Days		Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070432	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201801-000052			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Hypersensitivity; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Oral	Unk	Concordia
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	20 Mg	Not Reported
	Leflunomide	S	Unknown	20 Mg	Not Reported
	Actemra	S	Subcutaneous	Unk Unk, Weekly	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg, Weekly	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	Unk, Qcy	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	20 Mg, Weekly	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Xeljanz	C		Unk	Not Reported
	Meloxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070436	EXPEDITED (15-DAY)		OT	ALC2020CA005784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Fish Oil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	12.5 Mg, Qd		Not Reported
	Buprenorphine			S	Unknown	10 Mg, Qd		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cyanocobalamin			S	Unknown	Unk		Not Reported

	Furosemide;Potassium Chloride	S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]	S	Unknown	20 Mg		Not Reported
	Magnesium	S	Unknown	Unk		Not Reported
	Magnesium Gluconate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Pyridoxine Hydrochloride	S	Unknown	Unk		Not Reported
	Ramipril	S	Unknown	12.5 Mg, Qd		Not Reported
	Rivaroxaban	S	Unknown	15.0 Mg, Qd		Not Reported
	Vitamin B6	S	Unknown	Unk		Not Reported
	Vitamin D Nos	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070483	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03708		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Alteplase			S	Intravenous (not otherwise specified)	25 Milligram (Over 2 Hours)		Not Reported
	Alteplase			S	Intravenous (not otherwise specified)	25 Milligram (Over Subsequent 22 Hours)		Not Reported
	Alteplase			S				Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported
	Phenylephrine			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	10 Units/Kg/H		Not Reported
	Heparin			C				Not Reported
	Vasopressin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18070956	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1805869		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)			Not Reported
	Perindopril			C	Unknown			Not Reported
	Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071202	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059466		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Lyrica			S	Unknown	150 Milligram		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown	365 Milligram		Not Reported
	Bimatoprost			C	Ophthalmic	Unk, Qd		Not Reported
	Esomeprazole			C	Unknown	40 Milligram, Qd		Not Reported
	Nexium [Esomeprazole Sodium]			C	Unknown	40 Milligram, Qd		Not Reported

Sulfasalazine	C	Unknown	1000 Milligram, Bid		Not Reported
Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown	10 Milligram, Qd		Not Reported
Trazodone	C	Unknown	200 Milligram, Qd		Not Reported
Tylenol	C	Unknown	300 Milligram		Not Reported
Valsartan	C	Unknown	Unk, Qd		Not Reported
Wellbutrin	C	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071238	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071239	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805443			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Arthritis	Enbrel		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071240	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Etanercept		C	Unknown	Not Reported
	Humira		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071242	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805453		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071250	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805200		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071503	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-254929		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide			C	Unknown	Single Tablet Regimen, Unk		Not Reported
	Sarilumab			C	Intravenous (not otherwise specified)	200 Milligram, Unk		Not Reported
	Sarilumab			C	Intravenous (not otherwise specified)	200 Milligram, Unk,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071506	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-254927		78 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown			Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071537	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805231		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Advil [Ibuprofen]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071539	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804889		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071540	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory	Leflunomide			S	Unknown			Barr

Disorder; Rheumatoid Arthritis	Methotrexate		S	Unknown	Barr
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Desoximetasone		C		Not Reported
	Hydroxychloroquine Sulfate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071546	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805628			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071699	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1804623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

	Cosentyx	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Otezla	S	Oral			Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Stelara	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071700	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg,1 Every 1 Week		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071713	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1804687			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071716	NON-EXPEDITED		DE, OT	CA-AMGEN-CANSP2020119472		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen

Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Actemra	S	Unknown	Unk	Not Reported
	Doxycycline Hyclate	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Rituximab;Urelumab	C	Unknown	Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071723	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1804767			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071726	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804766		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported

Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071943	EXPEDITED (15-DAY)		OT	CA-ACCORD-192305		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Certolizumab			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S				Not Reported
	Orencia			S				Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18071947	EXPEDITED (15-DAY)		OT	CA-ACCORD-192361			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form:Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072247	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202007007174			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Raltegravir			C		Unk		Not Reported
	Emtricitabine			C		Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C		Unk		Not Reported
	Antithymocyte Immunoglobulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072261	EXPEDITED (15-DAY)		OT	CA-ACCORD-192217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swollen Joint Count Increased; Tender Joint Count Increased	Methotrexate	S	Unknown			Accord
	Celebrex	S	Oral	2 Every 1 Days		Not Reported
	Folic Acid	S	Oral	1 Every 1 Days		Not Reported
	Hydroxychloroquine	S	Oral	1 Every 1 Days		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Naproxen	S	Oral	2 Every 1 Days		Not Reported
	Ergocalciferol	C	Oral	M 1 Every 1 Days		Not Reported
	Lansoprazole	C	Oral	1 Every 1 Days		Not Reported
	Paroxetine	C	Oral	1 Every 1 Days		Not Reported
	Prazosin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072262	EXPEDITED (15-DAY)		OT	CA-ACCORD-192148			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Salazopyrin			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072277	EXPEDITED (15-DAY)		DS	CA-ACCORD-192211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness;	Methotrexate			S	Oral			Accord
	Apo-Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S		1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported

Nasopharyngitis; Neck Deformity; Neck Mass; Pain	Indocid	S			Not Reported
	Leflunomide	S		1 Every 1 Days	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Every 1 Days	Not Reported
	Actemra	S			Not Reported
	Cymbalta	C	Oral	1 Every 1 Days	Not Reported
	Xeljanz	C			Not Reported
	Methotrexate	S	Oral	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Days	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Apo-Prednisone	S	Oral	1 Every 1 Days	Not Reported
	Apo-Prednisone	S	Oral	1 Every 1 Days	Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072279	EXPEDITED (15-DAY)		OT	CA-ACCORD-192146			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported
	Leflunomide			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S				Not Reported

	Acetylsalicylic Acid	C	1 Every 1 Days	Not Reported
	Tiaprofenic Acid	C	1 Every 1 Days	Not Reported
	Hydroxychloroquine	S	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072368	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059486		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072468	EXPEDITED (15-DAY)		OT	CA-ACCORD-192486			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072469	EXPEDITED (15-DAY)		OT	CA-ACCORD-192485		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072474	EXPEDITED (15-DAY)		OT	CA-ACCORD-192496		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S		1 Every 1 Weeks		Accord
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Enbrel			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Synthroid			C				Not Reported
	Pantoprazole			C				Not Reported
	Omnaris			C				Not Reported
	Norflex			C				Not Reported
	Loperamide			C				Not Reported
	Lasix			C				Not Reported
	Vagifem			C				Not Reported
	Diphenhydramine			C				Not Reported
	Dilaudid			C				Not Reported
	Darifenacin/Darifenacin Hydrobromide			C				Not Reported
	Ativan			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072483	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072484	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804708			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

	Lyrica	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072485	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804776		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cephalexin [Cefalexin]			C	Unknown	2000 Milligram Daily;		Not Reported
	Perindopril			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072511	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1805431		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Leflunomide			S	Oral			Barr

Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Subcutaneous		Barr
	Cefazolin		S	Unknown		Not Reported
	Apo-Leflunomide		S	Oral		Not Reported
	Arava		S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Naproxen		C	Unknown		Not Reported
	Viread		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072512	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804853		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Actemra		C	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072608	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073007	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Increased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1.2 Milliliter		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073013	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805550		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid	C			Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073014	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804591		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Elavil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C				Not Reported
	Tenormin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073217	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804709			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073218	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2020-CA-1804883			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported

	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073279	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1066993		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysbiosis; Liver Injury; Off Label Use; Pneumatosis Intestinalis	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Enoxaparin			S	Subcutaneous	4000ui		Not Reported
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Qd,Loading Dose Unknown		Not Reported
	Piperacillin/Tazobactam			S	Unknown	4.5 Gram, Tid,Dose: 4.5g Three Times Daily		Not Reported
	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported
	Lactulose			S	Unknown	25 Milliliter, Qd,Dose: Average Dose Of 25ml Per Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Paracetamol			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073292	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1805441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Leflunomide	S	Oral			Barr
	Methotrexate	S	Subcutaneous			Barr
	Cefazolin	S	Unknown			Not Reported
	Apo-Leflunomide	S	Oral			Not Reported
	Enbrel	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Arava	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Viread	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804628			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073298	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1805547		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Sleep Disorder; Spinal Stenosis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Acetaminophen/Tramadol Hydrochloride			S	Oral			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Risedronate Sodium			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073307	EXPEDITED (15-DAY)		HO, OT	TH-LUPIN PHARMACEUTICALS INC.-2020-03570		58 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Darunavir			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Lupin
	Ritonavir			S	Unknown	Unk		Not Reported
	Favipiravir			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Decreased For 50%		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Continued With Dose Of 2.5 Milligram, Qd		Not Reported
	Basiliximab			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Manidipine			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Glipizide			C	Unknown	Unk		Not Reported
	Co-Trimoxazole			C	Unknown	Unk		Not Reported
	Acyclovir [Aciclovir]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073309	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03569		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Gabapentin			S	Unknown	Unk, 300 Mg In The Morning And 600 Mg At Night		Lupin
	Gabapentin			S	Unknown	Additional Doses		Lupin
	Gabapentin			S	Unknown	900 Milligram, Tid		Lupin
	Fingolimod			C	Unknown	Unk		Not Reported
	Fremanezumab			C	Unknown	Unk, Past 1 Year		Not Reported
	Tizanidine			C	Unknown	2 Milligram, Nightly		Not Reported
	Diphenhydramine			C	Intravenous (not otherwise specified)	Unk Unk, Tid		Not Reported
	Promethazine			C	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Prochlorperazine			C	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Valproic Acid			C	Unknown	Unk		Not Reported
	Ondansetron			C	Unknown	Unk, Tid		Not Reported
	Morphine			C	Unknown	Unk, Used Sparingly		Not Reported
	Hydromorphone			C	Unknown	Unk, Used Sparingly		Not Reported
	Lacosamide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073311	EXPEDITED (15-DAY)		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03625		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd		Lupin
	Venlafaxine			S	Unknown	225 Milligram, Qd		Not Reported

	Lopinavir + Ritonavir	S	Unknown	1 Dosage Form, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073312	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804765		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cetirizine			C				Not Reported
	Cranberry			C				Not Reported
	Olopatadine			C				Not Reported
	Prednisone			C				Not Reported
	Quinapril Hydrochloride			C				Not Reported
	Rabeprazole			C				Not Reported
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073339	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1804725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073340	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805551		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Simponi	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Actemra	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Prednisone	C	Unknown	12 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073349	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804738		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073352	EXPEDITED (15-DAY)		HO	CA-MYLANLABS-2020M1066966		11 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Victim Of Child Abuse	Ascorbic Acid			S	Oral	1500 Milligram, Qd		Not Reported
	Baclofen			S	Oral	20 Milligram, Tid Administered Three Times Daily		Not Reported
	Diphenhydramine			S	Oral	12.5 Milligram, Q6h Administered Every 6 Hours As Required		Not Reported
	Fluoxetine			S	Oral	20 Milligram, Qd		Not Reported
	Gabapentin			S	Oral	600 Milligram, Tid Administered Three Times Daily		Not Reported
	Ranitidine			S	Oral	150 Milligram, Qd		Not Reported
	Celecoxib			S	Oral	100 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Melatonin			S	Oral	10 Milligram, Qd Administered Every Night		Not Reported
	Pantoprazole			S	Oral	40 Milligram, Qd		Not Reported
	Montelukast			S	Oral	10 Milligram, Qd		Not Reported
	Bisacodyl			S	Oral	5 Milligram, Qd Administered Daily As Required		Mylan
	Colecalciferol			S	Oral	2000 International Unit, Qd		Mylan
	Aripiprazole			S	Oral	2 Milligram, Tid Administered Three Times Daily		Mylan
	Clobazam			S	Oral	20 Milligram, Bid		Mylan
	Clonidine			S	Oral	Dose: 0.05mg Every		Mylan

			Morning And 0.1 Mg Every Evening	
Dimenhydrinate	S	Oral	25 Milligram, Qd Administered Daily As Required	Mylan
Ketorolac	S	Oral	20 Milligram, Q6h Administered Every 6 Hours As Required	Mylan
Leuprorelin	S	Intramuscular	7.5 Milligram Every 30 Days	Mylan
Lorazepam	S	Sublingual	Dose: 0.5mg And 2mg, As Required	Mylan
Methocarbamol W/Paracetamol	S	Oral	Unk, Bid	Mylan
Methadone	S	Oral	2 Milligram, Tid Administered Three Times Daily	Mylan
Hydromorphone	S	Unknown	Immediate Release	Mylan
Phenobarbital	S	Oral	30 Milligram, Bid	Mylan
Polyethylene Glycol	S	Oral	30 Milligram, Bid	Mylan
Salbutamol Sulfate	S	Respiratory (inhalation)	2 Dosage Form, Q4h 100microg Per Actuation; 2 Puffs Every 4 Hours As Required	Mylan
Fluticasone	S	Respiratory (inhalation)	2 Dosage Form, Qd Dose: 250microg Per Actuation; 2 Puffs Daily	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073399	EXPEDITED (15-DAY)		OT	CA-ACCORD-192308		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product	Methotrexate			S	Unknown			Accord
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Esomeprazole		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Naproxen		C		Not Reported
	Xeljanz		C	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073400	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-192312		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Blindness Unilateral; Condition Aggravated; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Methotrexate			S	Unknown			Accord
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported
	Prednisone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073404	EXPEDITED (15-DAY)		OT	CA-ACCORD-192150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain;	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Single Used Prefilled Syringe	Not Reported
	Cortisone	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S			Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073408	EXPEDITED (15-DAY)		HO	CA-ACCORD-192313		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Sputum Discoloured; Thrombosis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S		Frequency: 1 Every 4 Hours		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S				Not Reported
	Warfarin			S				Not Reported
	Amitriptyline			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073416	EXPEDITED (15-DAY)		OT	CA-ACCORD-192077		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Methotrexate			S		1 Every 1 Weeks		Not Reported
	Aclasta			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S		1 Every 1 Days		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneou		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported
	Tramacet			S				Not Reported
	Tylenol			C				Not Reported
	Risedronic Acid			C		1 Every 1 Weeks		Not Reported
	Nortriptyline			C				Not Reported
	Metformin			C		1 Every 1 Days		Not Reported
	Lyrica			C	Oral	2 Every 1 Days		Not Reported
	Methylprednisolone			C				Not Reported
	Ergocalciferol			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Lorazepam			C		1 Every 1 Days		Not Reported
	Premarin			C				Not Reported
	Vagifem			C				Not Reported
	Arava			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Metformin			C		2 Every 1 Days		Not Reported
	Methylprednisolone			C	Intramuscular	1 Every 1 Months		Not Reported
	Methylprednisolone			C	Subcutaneous	1 Every 1 Months		Not Reported
	Nortriptyline			C		1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073433	EXPEDITED (15-DAY)		OT	CA-ACCORD-192080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073435	EXPEDITED (15-DAY)		OT	CA-ACCORD-192149			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate	S				Accord
	Actemra	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral	1 Every 1 Days		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S				Not Reported
	Prednisone	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073436	EXPEDITED (15-DAY)		HO	CA-ACCORD-192151			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Below Normal; Human Antichimeric Antibody Positive; Joint Destruction; Polyarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Wheelchair User	Methotrexate			S		1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S				Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Etanercept			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Folic Acid			C				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Immunoglobulin (Immunoglobulin G Human)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Naproxen			S				Not Reported
	Orencia			S	Intravenous (not	1 Every 1 Months		Not Reported

		otherwise specified)		
Prednisone	S			Not Reported
Sulfasalazine	S	Oral	1 Every 1 Days	Not Reported
Triamcinolone	S		-31.0	Not Reported
Methotrexate	S		1 Every 1 Weeks	Accord
Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Every 2 Weeks	Not Reported
Anakinra	S	Subcutaneous	1 Every 1 Weeks	Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Subcutaneous	1 Every 1 Days	Not Reported
Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
Etanercept	S	Subcutaneous	1 Every 1 Weeks	Not Reported
Hydroxychloroquine	S			Not Reported
Immunoglobulin (Immunoglobulin G Human)	S	Intravenous (not otherwise specified)		Not Reported
Immunoglobulin (Immunoglobulin G Human)	S	Intravenous (not otherwise specified)		Not Reported
Immunoglobulin (Immunoglobulin G Human)	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	1 Every 6 Weeks	Not Reported
Infliximab	S			Not Reported
Orencia	S	Intravenous drip	1 Every 1 Months	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported

Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
Prednisone	S	Oral	2 Every 1 Day		Not Reported
Prednisone	S	Oral	2 Every 1 Days		Not Reported
Triamcinolone	S				Not Reported
Triamcinolone	S	Intra-articular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073440	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1067335		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Hypoxia; Off Label Use; Respiratory Failure	Dexamethasone			S	Unknown	Drd Regimen		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Daratumumab			S	Unknown	Drd Regimen		Mylan
	Lenalidomide			S	Unknown	Drd Regimen		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073458	EXPEDITED (15-DAY)		OT	UG-LUPIN PHARMACEUTICALS INC.-2020-03656		34 YR	Female	UGA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	400 Mg Twice Daily On Day 3		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (200 Mg Twice Daily For The Subsequent 5 Days)		Lupin
	Tenofovir Disoproxil Fumarate			S	Unknown	Unk		Not Reported
	Lamivudine			C	Unknown	Unk		Not Reported

	Efavirenz	C	Unknown	Unk	Not Reported
	Paracetamol	C	Unknown	1 Gram, Tid (Three Times Daily For 5 Days)	Not Reported
	Ciprofloxacin	C	Oral	500 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073460	EXPEDITED (15-DAY)		HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2020-03682		62 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asymptomatic Covid-19; Cardiac Infection; Covid-19; Leukopenia; Nosocomial Infection; Off Label Use; Sars-Cov-2 Test Positive	Hydroxychloroquine			S	Unknown	400 Milligram, Bid, Loading Dose From Day 7		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid, Received Till Day 14		Lupin
	Mycophenolate Mofetil			S	Unknown	500 Milligram, Bid		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Cyclosporine A			S	Unknown	Target Range 135 +- 30 Ng/Ml		Not Reported
	Valganciclovir			C	Unknown	Unk		Not Reported
	Cotrimoxazole			C	Unknown			Not Reported
	Ganciclovir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073537	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1804693		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Atenolol	C	Oral	50 Milligram Daily;		Not Reported
	Hydrochlorothiazide	C	Oral	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073612	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1804724			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073652	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-058225		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Off Label Use; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	10 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	0.8 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	10 Milligram		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073656	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804730		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait	Leflunomide			S	Oral			Barr

Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Methotrexate		S	Subcutaneous	Barr
	Apo-Leflunomide		S	Unknown	Not Reported
	Certolizumab Pegol		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous	Not Reported
	Otezla		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073724	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804781		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073725	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1804694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Subcutaneous	Barr
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Abatacept	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073726	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1805198		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity;	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Adalimumab	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073763	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Gold	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown			Not Reported
Sulfasalazine	S	Unknown	1 Gram Daily;		Not Reported
Lyrica	C	Oral			Not Reported
Prednisone	C	Oral	15 Milligram Daily;		Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073767	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1805462		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073768	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805545		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cymbalta			C				Not Reported
	Elavil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex [Sumatriptan]			C				Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C				Not Reported
	Sumatriptan Succinate			C				Not Reported
	Tenormin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073815	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea;	Leflunomide			S	Unknown			Barr

Oral Discomfort; Uveitis	Methotrexate		S	Subcutaneous	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe		C	Subcutaneous	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073816	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804713			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intratumor			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073849	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-03750		70 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Uveitis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073954	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1066466		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Syncope	Sotalol			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	500 Milligram, Cycle, Single		Not Reported
	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Milligram, Qd, 200 Milligram, Tid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073962	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1066463		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Azithromycin			S	Oral	500 Milligram, Single		Not Reported
	Levomepromazine			S	Unknown	Unk		Mylan
	Zuclopenthixol			S	Unknown	Unk		Mylan
	Hydroxychloroquine Sulfate			S	Oral	200 Mg/L, Tid		Mylan
	Alimemazine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18074170	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805509		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm	Methotrexate			S	Subcutaneous	25 Mg		Barr

Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline		S	Unknown		Actavis
	Apo-Azathioprine		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18074504	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059441		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Oral			Not Reported
Xeljanz	C	Oral	5 Milligram, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18076453	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3496290-00		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema Nodosum; Off Label Use; Therapeutic Response Unexpected	Lopinavir/Ritonavir			S	Oral	200/50mg 2 Tables		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18077259	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805508		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Minocycline			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sirukumab	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Ustekinumab	S	Unknown			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Orencia	C	Intravenous (not otherwise specified)			Not Reported
Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18077296	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805454		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Hydromorphone Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18077309	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016534951		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported

Leflunomide	S	Unknown	20 Milligram		Not Reported
Leflunomide	S	Oral	20 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	11695383	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015115178		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Enbrel			S	Subcutaneous	Unk		Amgen
	Celebrex			S	Oral	200 Milligram, As Necessary		Not Reported
	Celebrex			S	Oral	200 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram, Bid		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	12091497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016085227		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly (50 Milligram, Qwk)		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Ng, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S		Taken For 2 Years		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (Qwk)		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	400 Mg, Taken For 2 Years		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Humira			S		40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Apo-Azathioprine	S	Unknown	100 Mg, Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	50 Mg, Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	100 Mg, Unk	Not Reported
Arava	S	Oral	20 Mg, Weekly	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg, 1x/Day	Not Reported
Apo-Minocycline	S	Unknown	50 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk, Monthly (Qmo)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Clavulin	C		Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported

Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)		Not Reported
Bcg Vaccine	C	Unknown	Unk (Powder For Solution For Intravesical Use)		Not Reported
Adalimumab	C		Unk		Not Reported
Risedronate	C	Oral	35 Mg, Qwk		Not Reported
Amoxicillin	C		Unk		Not Reported
Amoxil [Amoxicillin Trihydrate]	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C	Subcutaneous	400 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	12568992	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1675501-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	12705597	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1521		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Fosamax	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Lisinopril	C	Unknown	Not Reported
	Vit D3	C	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported
	Fosavance	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Mtx	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	12771268	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076851		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Decreased; Treatment Noncompliance	Gold		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Sodium Aurothiomalate		S	Intramuscular		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	14198647	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3616		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	2 Times/Week		Not Reported
	Enbrel			S	Unknown	2x/Week (2 Every 1 Week)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	2 Times/Wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown	Cyclical		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Cyclical	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Wellbutrin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	14235038	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021663		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk (Cyclical)		Apotex
	Hydroxychloroquine			S	Oral	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	1 Df, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, 1 Every 1 Hour		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk (Cyclical)		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex
	Risedronate			S	Unknown	Unk		Apotex
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actonel			S	Unknown	35 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	300 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported

Cimzia	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Risedronic Acid	S	Oral	35 Mg, Q.Wk.		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk (Cyclical)		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	10 Mg, Qd		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
Risedronate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	14628698	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037929		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Xeljanz	S	Oral	5 Milligram, Q2wk		Not Reported
Xeljanz	S	Oral	5 Milligram, Every One Day		Not Reported
Xeljanz	S	Oral	5 Milligram, Q2wk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Lyrica	S	Oral	Unk		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Prednisone	C	Oral	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Codeine	C	Unknown	Unk		Not Reported
Lyrica	C				Not Reported
Xeljanz	C	Oral	5 Milligram, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	15231584	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015216365		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Zostavax	S	Subcutaneous	Unk (Powder For Suspension)	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	15291706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015415739		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Prednisone	C	Oral	10 Milligram, Qd		Not Reported
Prednisone	C	Oral	6 Milligram, Qd		Not Reported
Mefenamic Acid	C	Unknown	Unk		Not Reported
Advil	C	Unknown	Unk		Not Reported
Dequalinium Chloride	C		Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	15333552	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP019423		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydrochlorothiazide			S	Oral	25 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Atenolol	C	Oral	50 Mg, Qd		Not Reported
Hydrochlorothiazide	C	Oral	25 Mg, Qd		Not Reported
Infliximab	C	Intravenous (not otherwise specified)	300 Mg, Qd		Not Reported
Simponi	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	15389857	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082887		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram, Q4wk, 84 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported

Decreased; Weight Increased	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram, Qmo	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram, Qmo	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	725 Milligram, Q4wk	Not Reported
	Chlorhexidine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Periarticular	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported
	Oxycodone Actavis	S	Unknown	Unk	Not Reported
	Periogard	S	Buccal	Unk	Not Reported
	Chloraprep One Step	S	Topical		Not Reported
	Apo Acetaminophen	S	Unknown	Unk	Not Reported
	Arava	C	Oral	20 Milligram, Qd	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Desogestrel And Ethinyl	C	Unknown	Unk	Not Reported

Estradiol				
Ibuprofen	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Milligram	Not Reported
Prednisone	C	Oral	1 Dosage Form, Qd	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	10 Milligram, Bid	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Paracetamol Codeine	C	Unknown	Unk	Not Reported
Cetrizine	C	Unknown	Unk	Not Reported
Plaquenil S	C	Unknown		Not Reported
Marvelon 28	C	Unknown		Not Reported
Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	15543164	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016253265		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed	Enbrel			S	Subcutaneous	40 Mg, Weekly		Unknown
	Enbrel			S	Subcutaneous	40 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer

Underdose; Product Use Issue; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	8.0 Mg/Kg	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Mg, Monthly	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk (Powder And Solvent For Solution For Injection/Infusion)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, 1x/Day (Every 24 Hours)	Not Reported
	Prednisone	C	Unknown	10 Mg, 2x/Day	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	15599232	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018458049		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Unknown	5 Milligram		Pfizer
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	5 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Not Reported
	Prednisone			C	Unknown	50 Mg, 1x/Day		Not Reported
	Prednisone			C		Qwk, (Endocervical Route)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	16048932	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018185639		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy;	Enbrel			S	Unknown	Unk		Pfizer

Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Migraine; Miliaria; Nausea; Off Label Use; Oral Pain; Pain In Extremity; Pancreatitis; Peripheral Swelling; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	50 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	20 Milligram, Qwk	Pfizer
	Celecoxib	S	Unknown	200 Milligram, Q12h	Pfizer
	Sulfasalazine	S	Unknown	1 G, 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	Unk, 11:1 Mg	Pfizer
	Rituximab	S		Unk	Pfizer
	Morphine Sulfate	S	Unknown	Unk	Pfizer
	Morphine Sulfate	S	Intravenous (not otherwise specified)	Unk	Pfizer
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S			Not Reported
	Actemra	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Citalopram	C	Unknown	10 Mg, 1x/Day	Not Reported
	Citalopram	C		Unk	Not Reported

	Celebrex	C		200 Mg, 2x/Day	Not Reported
	Celebrex	C		Unk	Not Reported
	Lorazepam	C		1 Mg, 1x/ Day (At Bedtime)	Not Reported
	Lorazepam	C		Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Prednisone	C		Unk	Not Reported
	Pantoloc	C		40 Mg, 2x/Week	Not Reported
	Pantoloc	C	Unknown	40 Mg, 2x/Day	Not Reported
	Pantoloc	C		40 Mg, 2x/Day	Not Reported
	Pantoloc	C		40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	16933000	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2962653-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Vimovo			S	Unknown	Delayed And Immediate Release		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Septra			S	Unknown			Not Reported
	Ratio-Oxycocet			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

Pantoloc	S	Oral	Enteric Coated	Not Reported
Oxycodone And Acetaminophen	S	Unknown		Not Reported
Naproxen	S	Oral	Enteric Coated	Not Reported
Methotrexate	S	Subcutaneous	Solution	Not Reported
Methotrexate	S	Oral		Not Reported
Methylprednisolone Sodium Succinate	S	Unknown	Injection	Not Reported
Mobicox	S	Oral		Not Reported
Imuran	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Apo-Ranitidine	S	Oral		Not Reported
Apo-Ranitidine	S	Oral		Not Reported
Lyrica	S	Oral		Not Reported
Lyrica	S	Oral		Not Reported
Depo-Medrol	S	Intra-articular		Not Reported
Bactrim	S	Unknown		Not Reported
Bactrim	S			Not Reported
Apo-Naproxen	S	Oral	Enteric Coated (500 Mg)	Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Meloxicam	S	Unknown		Not Reported
Apo-Alendronate	S	Unknown		Not Reported
Elavil	S	Oral	10mg/5ml	Not Reported
Amitriptyline	S	Oral		Not Reported
Apo-Amitriptyline	S	Oral		Not Reported
Esomeprazole Magnesium Trihydrate	S	Unknown		Not Reported
Esomeprazole	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Trimethoprim	S	Unknown		Not Reported

	Ranitidine	S	Oral	Not Reported
	Pantoprazole	S	Oral	Not Reported
	Amitriptyline Pamoate	S	Oral	Not Reported
	Amitriptyline Hydrochloride	S	Oral	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Oxycocet	S	Oral	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Celecoxib	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17179968	EXPEDITED (15-DAY)		DE, OT	CA-PFIZER INC-2019541123		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism;	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Actemra	S	Unknown	Unk	Not Reported
	Aurothiomalate De Sodium	S	Unknown	Unk	Not Reported
	Aurothiomalate De Sodium	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	10 Mg, 1x/Day	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab/Urelumab	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17583875	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2523564		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Diastolic Abnormal; Bone Marrow Toxicity; C-Reactive Protein Increased; Intentional Product Use Issue; Neuropathy Peripheral; Off Label Use; Paraesthesia; Pelvic Pain; Platelet Count Decreased; Rash; Spinal Disorder; Thrombocytopenia	Rituxan	S	Intravenous (not otherwise specified)	1 Every Week For 4 Dose		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Unknown			Not Reported
	Actemra	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Acetaminophen	C	Oral			Not Reported
	Diphenhydramine	C	Oral			Not Reported
	Lyrica	C				Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17675107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Etanercept			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17768317	EXPEDITED (15-DAY)		HO	US-CELLTRION INC.-2020US022161			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Gastric Disorder; Impaired Work Ability; Infected Lymphocele; Inguinal Hernia; Pneumonitis; Poor Quality Sleep; Prostate Cancer; Psoriasis; Septic Shock; Urticaria	Infliximab (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methylprednisolone Acetate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17808150	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES129943		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Interaction; Drug Level Increased; Drug Level Therapeutic; Gastrointestinal Disorder; Nephropathy Toxic; Off Label Use; Product Use In Unapproved Indication; Renal Failure	Lopinavir,Ritonavir			S	Oral	200/100 Mg, Bid		Not Reported
	Lopinavir,Ritonavir			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 5-10 Days)		Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	800 Mg, For 24 Hours Started On Day 5		Novartis
	Tacrolimus			S	Unknown	Reduce Dose		Not Reported
	Tacrolimus			S				Not Reported
	Mycophenolic Acid			C	Unknown	Dose Reduce		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17844876	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608720		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17846467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606512		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Risedronate Sodium	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17850050	EXPEDITED (15-DAY)		DS	CA-BAUSCH-BL-2020-015793		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Topicort			S	Cutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17900601	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-JNJFOC-20200616177			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Joint	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Arthroplasty; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Decreased; Rheumatoid Arthritis; Septic Shock; Therapy Non-Responder; Vomiting; Weight Increased; Wheelchair User	Indomethacin /00003801/	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S		Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo Prednison	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxyquinoline Sulfate	S	Oral	Not Reported
	Immunoglobulin /00025201/	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Triamcinolone	S	Intra-articular	Not Reported
	Triamcinolone	S		Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17959051	EXPEDITED (15-DAY)			NVSC2020ES129945		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Below Therapeutic; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 5-10 Days)		Novartis
	Lopinavir,Ritonavir			S	Oral	200/100 Mg, Bid		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17974041	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200637724		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Vomiting; X-Ray Abnormal	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17974045	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200637717		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17987343	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3471322-00		68 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Covid-19 Treatment; Gamma-	Kaletra			S	Oral	1 Cp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 2xdia Po Em D0		Not Reported
	Insulin Human			C				Not Reported
	Rosuvastatin			C	Oral			Not Reported

Glutamyltransferase Increased; Hepatotoxicity	Clopidogrel	C	Oral			Not Reported
	Paracetamol	C	Oral			Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)			Not Reported
	Omeprazole	C	Oral			Not Reported
	Nolotil [Metamizole Magnesium]	C				Not Reported
	Bromazepam	C	Oral			Not Reported
	Metformin	C	Oral			Not Reported
	Valsartan	C	Oral			Not Reported
	Esomeprazole	C	Oral			Not Reported
	Nebivolol	C	Oral			Not Reported
	Enoxaparin Sodium	C				Not Reported
	Acetylsalicylic Acid	C	Oral	Ap S Refeicao		Not Reported
	Telmisartan	C	Oral	De Manha		Not Reported
	Bisoprolol	C	Oral			Not Reported
	Ursofalk	C	Oral			Not Reported
	Nolotil	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17990678	EXPEDITED (15-DAY)		DE	PT-ABBVIE-20K-130-3471279-00		81 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Diarrhoea; Renal Failure	Kaletra			S	Oral	2 Comp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 12/12h Em D0		Not Reported
	Salbutamol			C	Respiratory (inhalation)			Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)			Not Reported
	Losartan Potassium, Hydrochlorothiazide			C	Oral			Not Reported

	Buscopan	C	Oral	Not Reported
	Sodium Chloride	C	Intravenous (not otherwise specified)	Not Reported
	Epsicaprom	C	Oral	Not Reported
	Amoxicillin, Clavulanic Acid	C	Intravenous (not otherwise specified)	Not Reported
	Furosemide	C	Intravenous (not otherwise specified)	Not Reported
	Piperacillin, Tazobactam	C		Not Reported
	Captopril	C	Oral	Not Reported
	Clarithromycin	C	Intravenous (not otherwise specified)	Not Reported
	Glucosamine	C	Oral	Not Reported
	Enoxaparin Sodium	C		Not Reported
	Irbesartan	C	Oral	Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)	Not Reported
	Buscopan	C	Oral	Not Reported
	Amoxicillin, Clavulanic Acid	C	Intravenous (not otherwise specified)	Not Reported
	Losartan Potassium, Hydrochlorothiazide	C	Oral	Not Reported
	Epsicaprom	C	Oral	Not Reported
	Piperacillin -Tazobactam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18076723	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03946		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077019	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03924		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Decreased; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd		Lupin
	Metronidazole			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			S	Unknown	400/100 Mg, Bid		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Valproate			S	Unknown	1000 Milligram, Qd		Not Reported
	Valproate			S				Not Reported
	Olanzapine			C	Unknown	15 Milligram, Qd		Not Reported
	Olanzapine			C				Not Reported
	Mirtazapine			C	Unknown	15 Milligram, Qd		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077025	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-03733		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077038	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-03751		45 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Uveitis	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methotrexate			C	Unknown	7.5 Milligram Weekly		Not Reported

	Prednisolone		C	Unknown	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077144	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03923		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (Every 24 Hour)		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd (Every 24 Hour)		Lupin
	Paroxetine			S	Unknown	20 Milligram, Qd (Every 24 Hour)		Lupin
	Paroxetine			S	Unknown	10 Milligram, Qd (Every 24 Hour)		Lupin
	Topiramate			S	Unknown	150 Milligram, Qd (Every 24 Hour)		Lupin
	Topiramate			S				Lupin
	Risperidone			S	Unknown	4, 5 Mg, Qd		Not Reported
	Risperidone			S	Unknown	3 Milligram, Qd (Every 24 Hour)		Not Reported
	Lopinavir + Ritonavir			S	Unknown	400/100 Mg, Bid (Every 12 Hour)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077147	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03922		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	40 Milligram, Qd		Lupin
	Quetiapine			C	Unknown	200 Milligram, Qd		Not Reported

				(Interrupted)	
	Quetiapine	C	Unknown	200 Milligram, Qd (Gradually Reinstated)	Not Reported
	Lopinavir + Ritonavir	C	Unknown	400/100 Mg, Bid (Discontinued)	Not Reported
	Interferon Beta	C	Unknown	8mu, Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077323	EXPEDITED (15-DAY)		OT	CA-ACCORD-192465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Methotrexate			S	Unknown			Accord
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077324	EXPEDITED (15-DAY)		OT	CA-ACCORD-192458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Unknown			Accord
	Arava			S	Unknown	1 Every 1 Days		Not Reported
	Cimzia			S	Subcutaneous	Single Pre Filled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077378	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201808-002769			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod, Film-Coated Tablet		Concordia
	Predonine			S	Oral	20 Mg, Qd		Not Reported
	Predonine			S	Oral	60 Mg, Qd		Not Reported
	Predonine			S	Oral	50 Mg, Qd		Not Reported
	Predonine			S	Oral	40 Mg, Qd		Not Reported
	Predonine			S	Oral	30 Mg, Qd		Not Reported
	Predonine			S	Oral	25 Mg, Qd		Not Reported
	Predonine			S	Oral	20 Mg, Qd		Not Reported
	Predonine			S	Oral	15 Mg, Qd		Not Reported
	Bredinin			C		Unk		Not Reported
	Loxoprofen			C		Unk		Not Reported
	Aspara Potassium			C		Unk		Not Reported
	Pravastatin Na			C		Unk		Not Reported
	Urso			C		Unk		Not Reported
	Magnesium Oxide			C		Unk		Not Reported
	Rozerem			C		Unk		Not Reported
	Amitiza			C		Unk		Not Reported
	Bonalon			C		Unk		Not Reported
	Bonalon			C				Not Reported
	Nexium			C		Unk		Not Reported
	Nexium			C				Not Reported
	Micardis			C		Unk		Not Reported
	Lunesta			C		Unk		Not Reported

Furosemide	C	Unk	Not Reported
Flunitrazepam	C	Unk	Not Reported
Quetiapine	C	Unk	Not Reported
Etizolam	C	Unk	Not Reported
Alfacalcidol	C	Unk	Not Reported
Alfacalcidol	C		Not Reported
Nifedipine	C	Unk	Not Reported
Nauzelin	C	Unk	Not Reported
Calonal	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077649	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020120774		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Anakinra			S	Unknown	Unk		Not Reported
	Apo-Warfarin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18077762	EXPEDITED (15-DAY)		OT	CA-ACCORD-192562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frequent Bowel Movements; Rash; Retinal Toxicity; Stomatitis	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18078300	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-255410		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Azithromycin			S	Oral	Unk		Sun
	Azithromycin			S				Sun
	Methylprednisolone			S	Oral	16 Milligram, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Daily		Ipca
	Cyclosporine A			S	Unknown	Dose Reduced By Half		Not Reported
	Cyclosporine A			S				Not Reported
	Meropenem			C	Unknown	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	325 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18078383	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1805835		34 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown			Teva
	Paracetamol			S	Unknown	1000mg As Required.		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18078608	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805511		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Minocycline Hydrochloride	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Otezla	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18078644	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3494450-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Neutropenia; Synovitis; Unevaluable Event; Vasculitis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Arava	S	Unknown		Not Reported
Orencia	C			Not Reported
Xeljanz Xr	C			Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Cortisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18078703	EXPEDITED (15-DAY)		HO, OT	AU-GENERIC HEALTH PTY. LTD.-2020-02805		61 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Bacteraemia; Acute Kidney Injury; Burkholderia Pseudomallei Infection; Fixed Eruption; Hyperlactacidaemia; Hypotension; Hypoxia; Intervertebral Discitis; Leukocytosis; Neutrophilia; Normocytic Anaemia; Osteomyelitis; Pneumonia; Skin Hypopigmentation	Etanercept			S	Subcutaneous	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Sulfamethoxazole And Trimethoprim			S	Oral	Unk		Novel Labs
	Sulfamethoxazole And Trimethoprim			S	Intravenous (not otherwise specified)	Unk		Novel Labs
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079127	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059104		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Actemra	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079225	EXPEDITED (15-DAY)		OT	CA-ACCORD-192207		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic	Methotrexate			S	Intramuscular	Not Specified		Accord
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Arava			S	Oral			Not Reported

Product Effect Decreased	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Asa	C	Unknown	Not Specified		Not Reported
	Ergocalciferol	C	Unknown	Not Specified		Not Reported
	Lantus	C	Subcutaneous			Not Reported
	Lozide	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Prednisone	C	Unknown	Not Specified		Not Reported
	Ramipril	C	Unknown	Not Specified		Not Reported
	Methotrexate	S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079235	EXPEDITED (15-DAY)		OT	CA-ACCORD-192210		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Metaraminol			C				Not Reported
	Ativan			C				Not Reported
	Darifenacin/Darifenacin Hydrobromide			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C		Metered Dose		Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported

	Plantago Ovata/Plantago Ovata Husk	C				Not Reported
	Synthroid	C				Not Reported
	Vagifem	C		Vaginal Suppository		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079282	EXPEDITED (15-DAY)		OT	IR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-255444		41 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079637	EXPEDITED (15-DAY)		OT	NVSC2020US205547		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Hypoxia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid (5 Day Course)		Novartis
	Azithromycin			C	Unknown	Unk		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079666	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059092		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Penicillamine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1.0 Gram	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Amitriptyline Hydrochloride	C	Unknown		Not Reported
	Doxycycline	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Tobramycin	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079789	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1066467			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Off Label Use	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Azithromycin			S	Oral	500 Milligram, Single		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg/L, Tid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18079996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1805510		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective;	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis

Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Simponi	S	Unknown		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18080154	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2020M1067567		62 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	20 Milligram, Qw		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported
	Methotrexate			S				Not Reported
	Prednisolone			S	Unknown	20-25 Mg		Mylan
	Prednisolone			S	Unknown	5 Milligram, Qd		Mylan
	Prednisolone			S				Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan

	Hydroxychloroquine	S		Mylan
	Hydroxychloroquine	S		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18080184	NON-EXPEDITED			US-SA-2020SA193602			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18080232	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1067465		50 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Drug Interaction; Off Label Use; Respiratory Failure	Tacrolimus			S	Unknown			Not Reported
	Everolimus			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk Unk, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Mylan
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Mylan
	Thymoglobulin			S	Unknown			Mylan
	Prednisone			S	Unknown	D5 Milligram, Qd		Mylan
	Losartan			C	Unknown	50 Milligram, Bid		Mylan
	Acetaminophen			C	Unknown			Mylan
	Meropenem			C	Unknown			Mylan
	Meropenem			C				Mylan
	Interferon Beta			S	Subcutaneous	250 Microgram Q48h		Mylan
	Norepinephrine			C	Unknown			Mylan
	Ceftaroline			C	Unknown			Mylan
	Ceftaroline			C				Mylan

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18080258	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059133		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18080574	EXPEDITED (15-DAY)		HO, OT	ES-DEXPHARM-20200647		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine			S		225 Mg/24 H		Not Reported
	Azithromycin			S		250 Mg/24 H		Not Reported
	Lopinavir/Ritonavir			S		400/100 Mg/12 H		Not Reported
	Hydroxychloroquine			S		400 Mg/ 24 H		Not Reported
	Vortioxetine			C		10 Mg/24 H		Not Reported
	Trazodone			C		50 Mg/ 24 H		Not Reported
	Venlafaxine			S		150 Mg/24 H		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18081488	EXPEDITED (15-DAY)		OT	CA-ROCHE-2648996			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Discontinued		Not Reported
	Sulfasalazine			S	Unknown	Discontinued		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18081705	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806453		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18081836	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1806623			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate		S	Subcutaneous		Barr
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram Daily;	Not Reported
	Desoximetasone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18082472	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18082490	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806831		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18082509	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18082510	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806845		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18082561	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1806934		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Pain; Synovitis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18082664	EXPEDITED (15-DAY)		OT	CA-SA-2020SA194796			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Ramipril			S	Unknown	12.5 Mg, Qd		Sanofi
	Arava			S	Unknown			Sanofi
	Bisoprolol Salt Not Specified			S	Unknown	12.5 Mg, Qd		Not Reported
	Buprenorphine			S	Unknown	10 Mg, Qd		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cyanocobalamin			S	Unknown	Unk		Not Reported
	Fish Oil			S	Unknown	Unk		Not Reported
	Furosemide/Potassium Chloride			S	Unknown	Unk		Not Reported
	Lasix			S	Unknown	20 Mg		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Sanofi
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	15 Mg, Qd		Not Reported
	Pyridoxine Hydrochloride			S	Unknown			Not Reported
	Colecalciferol			S	Unknown	Unk		Not Reported
	Magnesium Gluconate			S	Unknown	Unk		Not Reported
	Magnesium Gluconate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	12419514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016264085		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Milligram, Qwk		Pfizer

Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate Sodium	S	Parenteral	25 Mg, Weekly	Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk, Weekly (For 20 Weeks)	Not Reported
	Gold	S		Unk, 1x/Day	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk Unk, Qwk	Not Reported
	Prednisolone	C		6 Milligram, Qd	Not Reported

	Tocilizumab	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd (One Every One Day)	Not Reported
	D-Penicillamine	C		Unk	Not Reported
	D-Penicillamine	C		Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Cyclosporine	C	Unknown	Unk	Not Reported
	Cyclosporine	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	6 Milligram, Bid	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Actemra	C	Unknown	Unk	Not Reported
	Phenylbutazone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	12716207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1611		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Onychoclasis; Synovitis; Tooth Loss	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Zostavax	S	Subcutaneous	Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Not Reported
Zostavax	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Cortisone	C	Subcutaneous	Not Reported
Cortisone	C	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Diclofenac	C	Oral	Not Reported
Diclofenac	C	Oral	Not Reported

	Diclofenac	C	Unknown	Not Reported
	Diclofenac	C	Subcutaneous	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Zostavax	C	Unknown	Not Reported
	Voltaren	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	12850287	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP012926		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	2000 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral			Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Other	Unk		Not Reported
	Abatacept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, (1 Every 2 Weeks)		Not Reported
	Humira			S	Subcutaneous	40 G, Unknown		Not Reported
	Humira			S	Subcutaneous	40 Mg, Bid		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Orencia	S	Subcutaneous	750 Mg, Q.Wk.		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Q.O.Wk.		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Tofacitinib	S	Unknown	Unk		Not Reported
Tofacitinib	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	13058525	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015728		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Azathioprine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	100 Milligram		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Anakinra	S	Subcutaneous	Unk		Not Reported
Anakinra	S	Unknown	100 Mg, Unk		Not Reported
Enbrel	S	Subcutaneous	25 Mg, Unk		Not Reported
Enbrel	S	Subcutaneous	Unk Unk, Q.Wk.		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Imuran /00001501/	S	Unknown	Unk		Not Reported
Imuran /00001501/	S				Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	100 Mg, Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Kineret	S	Unknown	100 Mg, Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	13063318	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0861		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Intra-arterial	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

	Apo Mycophenolate	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Unknown		Not Reported
	Teva Mycophenolate	S	Unknown		Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mycophenolate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown	Decrease Dose Weekly	Not Reported
	Prednisone	C	Unknown		Not Reported
	Piroxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	13075088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0547		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Contraindicated Product Administered; Diabetes Mellitus; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Oral	Not Reported
	Crestor	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	13128781	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017005116		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Mg, Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Mg, Bid		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Etanercept			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Arava			S	Unknown			Not Reported
	Rituximab			S	Unknown	1 Gram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6wk		Not Reported

Remicade	S	Unknown	300 Mg, Unk	Not Reported
Remicade	S	Unknown	300 Mg, Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Hydroxyquine	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
Methotrexate	S	Unknown	20 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	15 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
Methotrexate	S	Unknown	200 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Oral	Unk	Not Reported
Gold	S	Intramuscular	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

	Sulfasalazine		C	Unknown	1 G, Bid	Not Reported
	Wellbutrin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	13297479	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1173		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bedridden; Contraindicated Product Administered; Drug Intolerance; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg, As Needed (Half A Tablet)		Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported

Tylenol	C	Unknown	As Needed		Not Reported
Tylenol	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Desoximetasone	C	Unknown			Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported
Hydroxychloroquine	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	13563721	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017074123		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Q6wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituxan			S	Unknown	1000 Mg, Unk		Not Reported
	Rituxan			S	Unknown	2000 Mg, 1 Every 6 Months		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	2000 Mg, Unk (1000 Mg, 2 Doses Every 6 Months)		Not Reported
	Rituximab			S	Unknown	1000 Mg, Every 12 Weeks		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram Per Cubic Metre		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	10 Mg, Qwk		Not Reported
	Gold			C	Intramuscular	50 Mg, Qwk		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	13869128	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2456		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported

Elavil	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Imitrex	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Tenormin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Sumatriptan Succinate	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Amitriptyline	C	Unknown	Not Reported
Sumatriptan	C	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	14033431	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-017645		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervicobrachial Syndrome; Diffuse Alopecia; Erythema; Photodermatosis; Radiculopathy	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dekristol			C	Unknown			Not Reported
	Nebivolol			C	Unknown			Not Reported
	Palexia			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Thyronajod			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	14446503	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0985		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Overdose; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	2times/Wk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Vioxx			S	Oral			Not Reported
	Vioxx			S	Unknown			Not Reported
	Vioxx			S	Oral			Not Reported
	Vioxx			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	15575085	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015369675		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer

Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Celebrex	S	Oral	200 Mg, As Needed	Pfizer
	Celebrex	S	Oral	200 Mg	Pfizer
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	C	Unknown	200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	15592659	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014351856		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Unknown
	Enbrel			S	Subcutaneous	56 Mg, Weekly		Unknown
	Enbrel			S	Unknown	25 Milligram, Qwk		Unknown
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Parenteral	Unk		Pfizer

Methotrexate Sodium	S	Other	Unk	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Xeljanz	S	Oral	5 Mg, Twice A Day	Pfizer
Xeljanz	S	Oral	50 Milligram, Bid	Pfizer
Xeljanz	S	Oral	Unk, Bid	Pfizer
Xeljanz	S	Oral	5 Milligram, Q2wk	Pfizer
Xeljanz	S	Oral	5 Mbq, 2x/Day	Pfizer
Xeljanz	S	Unknown	Unk	Pfizer
Xeljanz	S	Oral	Unk, 2 Times/Wk	Pfizer
Azathioprine	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram, Bid	Not Reported
Humira	S	Unknown	40 Milligram, 2 Times/Wk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750 Milligram, Qwk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qwk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
Imuran	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	2000 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported

Actemra	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Tofacitinib	C		Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Bupropion	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	15635730	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1478917-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	3 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	15719015	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018156473		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	15917142	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007217		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	15978508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013850		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Orencia			S	Unknown	250 Mg, Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported

Myochrysine	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Otezla	S	Oral	Unk	Not Reported
Rituxan	S	Parenteral	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sirukumab	S	Unknown		Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Minocin	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Apremilast	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Prednisone	C	Unknown	5 Milligram	Not Reported
Methotrexate	C	Unknown	15 Mg, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Rheumatrex [Methotrexate Sodium]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	16139608	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0875			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	16148591	EXPEDITED (15-DAY)		OT	PHHY2019CA073512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic	Cosentyx			S	Oral	300 Mg, Qmo		Novartis
	Pantoprazole			S	Oral	1 Df, Qd(7.5 Mg)		Not Reported
	Leucovorin Calcium			S	Oral	5 Mg, Qw		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Diclofenac			S	Oral	Unk Unk, Tid		Not Reported

Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate	S	Oral	4 Df, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Meloxicam	S	Oral	7.5 Mg, Qd(1-2 Tab)	Not Reported
	Tecta	S	Unknown	Unk	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Tramadol Hcl	C	Oral	Unk Unk, Q24h (Biphasic 25-75)	Not Reported
	Salbutamol Sulfate	C	Respiratory (inhalation)		Not Reported
	Mar-Pantoprazole	C	Unknown		Not Reported
	Taro-Mometasone	C	Unknown		Not Reported
	Fluticasone Propionate	C	Respiratory (inhalation)		Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Diltiazem Hcl	C	Oral	240 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	16215711	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1200		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Urticaria	Enbrel	S	Unknown		Not Reported
	Cefazolin	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	Cyclical	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Amlodipine	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Naproxen	C	Unknown	50	Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Viread	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	17250391	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP026966		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Prednisone			S	Unknown	95 Mg, Qd		Not Reported
	Prednisone			S	Unknown	85 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd, 9 To 10 Mg		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd, 10 To 12 Mg		Not Reported
	Prednisone			S	Unknown	13 Mg, Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Apotex
	Lithium Carbonate			S	Unknown	Unk		Apotex
	Memantine			S	Unknown	Unk		Apotex
	Clonidine			S	Unknown	Unk		Apotex
	Mycophenolate			S	Unknown	Unk		Apotex
	Montelukast			S	Unknown	Unk		Apotex
	Cimetidine			S	Unknown	Unk		Apotex
	Amlodipine			S	Unknown	Unk		Apotex
	Pregabalin			S	Unknown	Unk		Apotex
	Diltiazem			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Naltrexone			S	Unknown	4.5 Mg, Qd		Apotex
	Pentoxifylline			S	Unknown	Unk		Apotex
	Calcitonin			S	Unknown	Unk		Not Reported
	Ketamine			S	Oral	Unk		Not Reported
	Ketamine			S	Topical	Unk		Not Reported
	Ketamine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lidocaine			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Lidocaine	S	Topical	Unk	Not Reported
	Apremilast	S	Unknown	Unk	Not Reported
	Ibudilast	S	Unknown	Unk	Not Reported
	Mexiletine	S	Unknown	Unk	Not Reported
	Metprolol	S	Unknown	Unk	Not Reported
	Magnesium	S	Unknown	Unk	Not Reported
	Magnesium	S			Not Reported
	Vitamin B 2	S	Unknown	Unk	Not Reported
	Vitamin B 2	S			Not Reported
	Capsaicin	S	Topical	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Palmitoylethanolamide	S	Unknown	Unk	Not Reported
	Spironolactone	S	Unknown	Unk	Not Reported
	Vitamin C /00008001/	S	Unknown	Unk (High Dose)	Not Reported
	N-Acetylcysteine	S	Unknown	Unk	Not Reported
	Bumetanide	S	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Ezetimibe	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	17350586	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Leflunomide	S	Unknown	20 Milligram		Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram		Not Reported
Meloxicam	C	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	17994473	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3471284-00		71 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Covid-19 Treatment; Gamma-Glutamyltransferase Increased	Kaletra			S	Oral	2 Cp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 12/12h Em D0		Not Reported
	Paracetamol			C	Oral			Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			C	Oral			Not Reported
	Bromazepam			C	Oral			Not Reported
	Diazepam			C	Oral			Not Reported
	Combodart			C	Oral			Not Reported
	Tamsulosin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18025302	EXPEDITED (15-DAY)		OT	CA-ACCORD-190396		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug	Methotrexate			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Desoximetasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18031651	EXPEDITED (15-DAY)		OT	CA-ACCORD-190411		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Methotrexate			S				Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Sulfasalazine			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S				Not Reported
	Actemra			S				Not Reported
	Hydromorphone/Hydromorphone Hydrochloride			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Cymbalta			C				Not Reported
	Synthroid			C				Not Reported
	Orencia			C	Unknown			Not Reported
	Simponi			C	Subcutaneous	Subcutaneous Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18041848	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1802698		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Long-Term Regimen		Not Reported
	Prednisone			C	Unknown	Long-Term Regimen		Not Reported
	Azithromycin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18041854	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1802697		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Long Term Therapy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18051169	EXPEDITED (15-DAY)		HO, LT, OT	CA-JNJFOC-20200721895		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Poor Venous Access; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Actemra	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous drip	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported

	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone	S	Subcutaneous	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18051674	EXPEDITED (15-DAY)		DS, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-22903		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme	Etanercept			S	Unknown	Unknown		Not Reported
	Acetaminophen			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Alendronate Sodium			S	Oral	Unknown		Not Reported
	Apo Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	Unknown		Not Reported

Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
	Cetirizine	S	Unknown	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown. Solution For Infusion In Pre-Filled Syringe	Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone	S	Oral	Unknown	Not Reported
	Cortisone	S	Oral	Unknown	Not Reported
	Cortisone	S	Unknown		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous	Unknown	Not Reported
	Desoximetasone	S	Oral	Unknown	Not Reported
	Desoximetasone	S	Oral	Unknown	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac	S	Unknown	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported

Enbrel	S	Unknown	Unknown	Not Reported
Enbrel	S	Subcutaneous	Unknown	Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown	Unknown	Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Fosamax	S	Oral	Unknown	Not Reported
Fosamax	S	Unknown	Unknown	Not Reported
Golimumab	S	Subcutaneous	Unknown	Not Reported
Golimumab	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Sunconjunctival	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Sunconjunctival		Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unknown	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Kevzara	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Leflunomide	S	Oral	Unknown	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported

Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Orencia	S	Subcutaneous	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Unknown	Not Reported
Plaquenil	S	Oral	Unknown	Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Oral	Unknown	Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown. Powder For Solution For Injection/Infusion	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown.	Not Reported
Rituxan	S	Intravesical	Unknown.	Not Reported
Sarilumab	S	Unknown	Unknown	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Stelara	S	Unknown	Unknown	Not Reported

Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown	Unknown	Not Reported
Topicort	S	Cutaneous	Unknown	Not Reported
Topicort	S	Oral	Unknown	Not Reported
Topicort	S	Oral	Unknown	Not Reported
Topicort	S	Subcutaneous	Unknown	Not Reported
Topicort	S	Cutaneous	Unknown	Not Reported
Topicort	S	Subcutaneous	Unknown	Not Reported
Topicort	S	Unknown	Unknown	Not Reported
Winpred	S	Oral	Unknown	Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown	Unknown	Not Reported
Zyrtec	S	Unknown		Not Reported
Atasol [Paracetamol]	C	Unknown	Unknown	Not Reported
Ibuprofen	C	Unknown	Unknown	Not Reported
Lisinopril	C	Unknown	Unknown	Not Reported
Salazopyrin	C	Unknown	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Unknown	Not Reported
Vitamin D3	C	Unknown	Unknown	Not Reported
Zyrtec-D	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18056921	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020020455			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Amgen
	Actemra	S	Unknown	162 Milligram, Qwk	Not Reported
	Apo-Prednisone	S	Unknown	1.0 Milligram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine Sodium	S	Oral	200 Milligram, Qd	Not Reported
	Depo-Medrol With Lidocaine	S	Intra-articular		Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Ketoprofen	S	Topical	Unk Unk, Qid	Not Reported
	Leucovorin Calcium	S	Unknown	1.0 Dosage Form, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	400 Milligram, Qd	Not Reported
	Prevnar 13	S	Intramuscular	0.5 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Azathioprine	S	Oral	200 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18058669	EXPEDITED (15-DAY)		OT	CA-ACCORD-191265		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal	Methotrexate			S	Oral	1 Every 2 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported

Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Humira	S	Subcutaneous	1 Every 2 Weeks, Solution Subcutaneous	Not Reported
	Leflunomide	S	Unknown	1 Every 1 Days	Not Reported
	Anakinra	S	Subcutaneous	1 Every 1 Days	Not Reported
	Orencia	S	Unknown	1 Every 4 Weeks	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Methotrexate	S	Oral	1 Every 2 Weeks	Accord
	Methotrexate	S	Oral	1 Every 1 Weeks, Not Specified	Accord
	Anakinra	S	Subcutaneous		Not Reported
	Orencia	S	Unknown	1 Every 1 Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18081964	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1807215			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Celecoxib			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown	2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18081986	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806804		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18081987	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18081995	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806947		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Desoximetasone	C				Not Reported
	Orencia	C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082013	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806757		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082019	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806753		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis; Treatment Failure	Arava		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Mobicox		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082020	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1806738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082022	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes	Methotrexate			S	Unknown			Barr

Zoster; Peripheral Swelling; Pneumonia Viral	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082656	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007355			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	200-400 Mg Daily Orally By Mouth Or Nasogastric Tube		Concordia
	Hydroxychloroquine			S				Concordia
	Baricitinib			C		Unk		Not Reported
	Lopinavir + Ritonavir			C		Unk		Not Reported
	Levofloxacin			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082679	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202007007377			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082945	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP014482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid	Azathioprine			S	Unknown	Unk		Not Reported

Arthritis	Cyclosporine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Methotrexate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	640 Milligram, Q.Wk.	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q.Wk.	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Q.Wk.	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18083073	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254772			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18083078	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202007007385			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Hypoglycaemia; Myocardial Infarction; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid (Q12h)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Levofloxacin			C				Not Reported
	Sulfamethoxazole;Trimethoprim			C				Not Reported
	Furosemide			C				Not Reported
	Paracetamol			C				Not Reported
	Enoxaparin			C				Not Reported
	Vecuronium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18083420	EXPEDITED (15-DAY)		OT	BR-LUPIN PHARMACEUTICALS INC.-2020-03868		57 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftaroline Fosamil			C	Unknown	Unk		Not Reported
	Actilyse			C	Intravenous (not otherwise specified)	18 Milligram, Unk		Not Reported
	Actilyse			C	Intravenous (not otherwise specified)	10 Milligram, Unk		Not Reported
	Atropine			C	Unknown	Unk		Not Reported
	Atropine			C				Not Reported
	Atropine			C				Not Reported
	Adenosine			C	Unknown	12 Milligram, Unk		Not Reported
	Noradrenaline (Norpinephrine)			C	Unknown	Unk		Not Reported
	Noradrenaline (Norpinephrine)			C				Not Reported
	Noradrenaline (Norpinephrine)			C				Not Reported
	Adrenaline [Epinephrine]			C	Unknown	Unk		Not Reported
	Adrenaline [Epinephrine]			C				Not Reported
	Adrenaline [Epinephrine]			C				Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Aspirine			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Unfractionated Heparin			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18083812	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS		74 YR	Male	ITA

INC.-2020-03818

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Coronary Artery Embolism; Intracardiac Thrombus; Myocarditis; Off Label Use; Stress Cardiomyopathy	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Dexamethasone			S	Unknown	20 Milligram, Qd		Not Reported
	Dexamethasone			S	Unknown	10 Milligram, Qd		Not Reported
	Dobutamine			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram (Per Minute)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084255	EXPEDITED (15-DAY)		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2020-03858		11 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Respiratory Depression; Victim Of Child Abuse	Polyethylene Glycol			S	Oral	30 Milligram, Bid		Novel Labs
	Lorazepam			S	Sublingual	Dose: 0.5mg And 2mg, As Required		Lupin
	Celecoxib			S	Oral	100 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Lupin
	Fluoxetine			S	Oral	20 Milligram, Qd		Lupin
	Clonidine			S	Oral	0.15 Milligram, Qd (0.05mg Every Morning And 0.1 Mg Every Evening)		Lupin
	Clobazam			S	Oral	20 Milligram, Bid		Lupin
	Aripiprazole			S	Oral	2 Milligram, Tid		Not Reported
	Hydromorphone			S	Unknown	Immediate Release		Not Reported
	Montelukast			S	Oral	10 Milligram, Qd		Not Reported
	Gabapentin			S	Oral	Administered Three Times		Not Reported

			Daily	
Ketorolac	S	Oral	Administered Every 6 Hours As Required	Not Reported
Ascorbic Acid	S	Oral	1500 Milligram, Qd	Not Reported
Ranitidine	S	Oral	150 Milligram, Qd	Not Reported
Fluticasone	S		Dose: 250microg Per Actuation; 2 Puffs Daily	Not Reported
Colecalciferol	S	Oral	2000 International Unit, Qd	Not Reported
Omega 3 Fish Oil [Docosahexaenoic Acid;Eicosapentaenoic Acid]	S	Oral	200-400-1000mg Daily	Not Reported
Phenobarbital	S	Oral	30 Milligram, Bid	Not Reported
Bisacodyl	S	Oral	5 Milligram, Qd (As Required)	Not Reported
Pantoprazole	S	Oral	40 Milligram, Qd	Not Reported
Melatonin	S	Oral	Administered Every Night	Not Reported
Methocarbamol;Paracetamol	S	Oral	Unk	Not Reported
Baclofen	S	Oral	20 Milligram, Tid	Not Reported
Salbutamol Sulfate	S		Dose: 100microg Per Actuation; 2 Puffs Every 4 Hours As Required	Not Reported
Methadone	S	Oral	Administered Three Times Daily	Not Reported
Leuprorelin	S	Intramuscular	7.5 Milligram Every 30 Day	Not Reported
Diphenhydramine	S	Oral	Administered Every 6 Hours As Required	Not Reported
Dimenhydrinate	S	Oral	Administered Daily As Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084283	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-03906		72 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aspergillus Infection; Drug Effective For Unapproved Indication; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Off Label Use; Pneumocystis Jirovecii Infection	Methylprednisolone	S	Oral	40 Milligram, Qd	Lupin
	Methylprednisolone	S	Oral	4 Milligram, Qd	Lupin
	Methylprednisolone	S	Oral	16 Milligram, Qd	Lupin
	Hydroxychloroquine	S	Oral	0.4 Gram, Qd	Lupin
	Hydroxychloroquine	S			Lupin
	Oseltamivir Phosphate	S	Unknown	Unk	Lupin
	Leflunomide	S	Oral	20 Milligram, Qd (For 10 Years)	Lupin
	Tocilizumab	S	Unknown	400 Milligram, Qd	Not Reported
	Tocilizumab	S	Unknown	400 Milligram, Qd	Not Reported
	Lopinavir/Ritonavir	C	Oral	1000 Milligram, Qd	Not Reported
	Lopinavir/Ritonavir	C	Oral	1000 Milligram, Qd	Not Reported
	Prednisone	C	Oral	10 Milligram, Qd	Not Reported
	Prednisone	C	Oral	50 Milligram, Qd	Not Reported
	Prednisone	C	Oral	75 Milligram, Qd	Not Reported
	Prednisone	C	Oral	150 Milligram, Qd	Not Reported
	Prednisone	C	Oral	125 Milligram, Qd	Not Reported
	Prednisone	C	Oral	100 Milligram, Qd	Not Reported
	Prednisone	C	Oral	60 Milligram, Qd	Not Reported
	Prednisone	C	Oral	37.5 Milligram, Qd	Not Reported
	Prednisone	C	Oral	25 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084586	EXPEDITED (15-DAY)		OT	CA-ACCORD-192820		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling;	Methotrexate			S	Unknown			Accord
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous,Single-Use		Not Reported

Liver Function Test Increased; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084588	EXPEDITED (15-DAY)		HO	CA-ACCORD-192821		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Ilaris			C	Subcutaneous	Single-Use Vial,Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084590	EXPEDITED (15-DAY)		OT	CA-ACCORD-192822		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084596	EXPEDITED (15-DAY)		OT	CA-ACCORD-192978		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper	Methotrexate			S				Accord
	Gold			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Mobicox			S				Not Reported
	Orencia			S				Not Reported
	Diclofenac			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			C				Not Reported
	Tocilizumab			C	Oral			Not Reported
	Actemra			S				Not Reported
	Leflunomide			S				Not Reported
	Methylprednisolone			C				Not Reported

Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084687	EXPEDITED (15-DAY)		OT	CA-ACCORD-192918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18084704	EXPEDITED (15-DAY)		OT	CA-ACCORD-192917		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Tylenol			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18085056	EXPEDITED (15-DAY)		OT	NVSC2020FR207580		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Azithromycin			S	Unknown	500 Mg, Qd		Novartis
	Azithromycin			S	Unknown	250 Mg, Qd(For 4 Days)		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Tid		Not Reported
	Levomepromazin			C	Unknown	Unk		Not Reported
	Zuclopenthixol			C	Unknown	Unk		Not Reported
	Alimemazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18085949	EXPEDITED (15-DAY)		OT	CA-ACCORD-192494		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S				Accord
	Orencia			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18085951	EXPEDITED (15-DAY)		OT	CA-ACCORD-192669			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertensive Urgency; Presyncope	Methotrexate			S	Oral			Accord
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported

	Humira	S	Unknown	2 Every 1 Weeks		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	C				Not Reported
	Folic Acid	C				Not Reported
	Humira	S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Methotrexate	S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18085975	EXPEDITED (15-DAY)		OT	CA-ACCORD-192974		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Methotrexate			S	Oral	1 Every 1 Weeks, Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown	1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086017	EXPEDITED (15-DAY)		OT	CA-ACCORD-192985		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Inflammation; Joint Swelling;	Methotrexate			S	Unknown			Accord

Musculoskeletal Stiffness; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Treatment Failure	Humira		S	Subcutaneous	Dosage Form:Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	Not Specified	Not Reported
	Leflunomide		C			Not Reported
	Prednisone		C		Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086026	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-193361			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Azithromycin			S		500 Mg Q.D.		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086072	EXPEDITED (15-DAY)		OT	CA-ACCORD-192972		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown	1 Every 24 Hours		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 24 Hours		Not Reported
	Prednisone			C	Unknown			Not Reported
	Celecoxib			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086411	EXPEDITED (15-DAY)		OT	CA-ACCORD-192697		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Methotrexate			S	Subcutaneous			Accord

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Hydroxychloroquine	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Ciclosporin	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Leflunomide	S			Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz Xr	C			Not Reported
	Methotrexate	S	Oral		Accord
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Neoral	S	Oral		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Xeljanz Xr	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086633	EXPEDITED (15-DAY)		OT	CA-ACCORD-192959		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	4 Every 1 Days	Not Reported
	Sulfasalazine		S	Unknown	4 Every 1 Days	Not Reported
	Leflunomide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086634	EXPEDITED (15-DAY)		OT	CA-ACCORD-192955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086637	EXPEDITED (15-DAY)		OT	CA-ACCORD-192813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Methotrexate			S				Accord
	Adalimumab			S	Subcutaneous	Frequency: 1 Every 2 Weeks		Not Reported
	Imuran			S		Frequency: 1 Every 1 Days		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Frequency: 1 Every 8 Weeks		Not Reported
	Plaquenil			S		Frequency: 1 Every 2 Days		Not Reported
	Rituximab			S	Intravenous (not	Frequency: 1 Every 15		Not Reported

				otherwise specified)	Days	
	Glyburide		C		Frequency: 1 Every 1 Days	Not Reported
	Lipitor		C		Frequency: 1 Every 1 Days	Not Reported
	Metformin		C	Oral	Frequency: 2 Every 1 Days	Not Reported
	Mycophenolic Acid		C	Oral	Frequency: 2 Every 1 Days	Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086643	EXPEDITED (15-DAY)		OT	CA-ACCORD-192958		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Arava			S	Intravenous (not otherwise specified)	1 Every 24 Hours		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 24 Hours		Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086647	EXPEDITED (15-DAY)		OT	CA-ACCORD-192968			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S				Not Reported
	Celebrex			S				Not Reported
	Bifidobacterium Bifidum			C				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Pantoprazole			C		3 Every 1 Days		Not Reported
	Loperamide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18086845	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059897		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	65 Milligram, Qwk		Not Reported

Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral	65 Milligram, Qwk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087086	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020287555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Ramipril			S	Unknown	12.5 Mg, Qd		Unknown
	Calcium Carbonate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Magnesium Sulfate			S	Unknown	Unk		Pfizer
	Cyanocobalamin			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	12.5 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Buprenorphine			S	Unknown	10 Mg, Qd		Not Reported
	Fish Oil			S	Unknown	Unk		Not Reported
	Furosemide/Potassium Chloride			S	Unknown	Unk		Not Reported
	Lasix [Furosemide]			S	Unknown	20 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	15 Mg, Qd		Not Reported
	Vitamin B6			S	Unknown	Unk		Not Reported
	Vitamin D [Colecalciferol]			S	Unknown	Unk		Not Reported
	Magnesium Gluconate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087121	EXPEDITED (15-DAY)		HO, OT	BR-LUPIN PHARMACEUTICALS INC.-2020-04073			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	12 Milligram, Qd		Lupin
	Methyldopa			S	Transplacental	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087267	DIRECT	Y	DE			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Ns Fluid			C				Not Reported
	Albumin 25%			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Potassium Chloride Ivpb			C				Not Reported
	Propofol			C				Not Reported
	Remdesivir			S				Not Reported
	Sodium Bicarbonate Large Volume			C				Not Reported
	Acetaminophen 500mg Tablet			C				Not Reported
	Ascorbic Acid Tablet			C				Not Reported
	Cholecalciferol 5000 Unit Tablet			C				Not Reported
	Dexamethasone 6mg Po Daily			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin 40mg Sq Q24h			C				Not Reported
	Enoxaparin 60mg Sq Q12h			C				Not Reported
	Etomidate Iv			C				Not Reported
	Furosemide 20mg Ivp			C				Not Reported
	Furosemide 40mg Ivp			C				Not Reported
	Insulin Aspart			C				Not Reported
	Ivermectin 12 Po X 1			C				Not Reported
	Ondansetron Ivp			C				Not Reported
	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087330	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087354	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806721		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806779		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Surgical Failure	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Mobicox		C	Unknown	15 Milligram Daily;	Not Reported
	Remicade		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088018	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1067554		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Tacrolimus			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Colchicine			S	Unknown	1 Milligram, Day 8		Mylan
	Colchicine			S	Unknown	0.5 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Mylan
	Mycophenolate Mofetil			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088113	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201901-000104			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	162 Mg		Not Reported

Decreased	Cimzia	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Imuran	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088128	EXPEDITED (15-DAY)		OT	NVSC2020FR207579		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Syncope	Azithromycin			S	Unknown	500 Mg, Qd		Novartis
	Azithromycin			S	Unknown	250 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088224	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806624		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

	Prednisone		C	Unknown		Not Reported
	Remicade		C	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088838	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059602		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia			S	Subcutaneous	250 Milligram		Bristol Myers Squibb
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	250 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088994	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1806682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088998	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088999	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089002	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806675		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089023	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1806401		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Hydrochlorothiazide			S	Oral			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Atenolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089024	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806598			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089070	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806684		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089095	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806787			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089142	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab/Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089148	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806402		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089155	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Swelling; Pain; Therapeutic Product Effect Decreased	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous	50 Milligram Daily;	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram Daily;	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	2 Gram Daily;	Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089157	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807040		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastrointestinal Disorder; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate			S	Unknown			Barr
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089187	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1806717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089189	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089191	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806687		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Boric Acid			S	Unknown			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Phenylephrine Hcl			S	Unknown			Not Reported
	Rho D Immune Globulin Human			S	Unknown			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown	10 Milligram Daily;		Not Reported
	Tofacitinib Citrate			S	Unknown	10 Milligram Daily;		Not Reported
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)			
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Ibuprofen	C	Oral			Not Reported
	Celebrex	C	Oral			Not Reported
	Lipitor	C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089220	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806602		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090657	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254398		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, 1dose/12hour		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, 1dose/12hour		Sun
	Azithromycin			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090807	EXPEDITED (15-DAY)		OT	CA-ACCORD-192948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported

Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelera	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Topicort	S	Oral	Not Reported
	Winpred	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Topicort	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090826	EXPEDITED (15-DAY)		OT	CA-ACCORD-192949		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S		Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Tofacitinib	S	Unknown	Not Reported
Topicort	S	Subcutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported
Atasol [Paracetamol]	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Hydrocortisone	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported

	Topicort		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	9643129	EXPEDITED (15-DAY)		OT	CA-ROCHE-1287733		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Fluctuation; Drug Hypersensitivity; Eye Disorder; Fatigue; Fibromyalgia; Infusion Related Reaction; Menopause; Oxygen Saturation Decreased; Pain; Rheumatoid Arthritis; Thermal Burn	Rituxan			S	Intravenous (not otherwise specified)	Most Recent Dose Prior To Sae: 06/May/2010, 17/Jun/2014, 26/Apr/2016		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Effexor			S	Unknown	Dosage Not Specified		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Arthrotec			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Nortriptyline			C		As Required		Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Doxycyclin			C				Not Reported
	Restasis			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Omega 3			C				Not Reported
	Quetiapine			C				Not Reported
	Venlafaxine			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	11519456	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015095516		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen

Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Enbrel	S	Subcutaneous	Unk Unk, Qwk	Amgen
	Enbrel	S	Unknown	Unk	Amgen
	Enbrel	S	Subcutaneous	Unk	Amgen
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk Unk, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Orencia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	400 Milligram, Qmo	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S			Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	1 Unk, Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Fosamax	S	Unknown	Unk	Not Reported

Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Milligram	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Other	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S	Unknown	Unk (Tablet)	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported

Prednisone	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	50 Milligram	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram (5mg/5ml)	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Tocilizumab	S	Unknown		Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1.0 Milligram	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported

Salazopyrin	C	Unknown	Unk		Not Reported
Atasol [Paracetamol]	C		Unk		Not Reported
Ibuprofen	C	Unknown	Unk		Not Reported
Lisinopril	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C		Unk		Not Reported
Prednisolone	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	11865597	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2012292491		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Xeljanz			S	Oral	5 Mg, 2x/Day (Q12h)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, Daily (2 In 1 Day)		Pfizer
	Xeljanz			S		12.5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day Qd (1 Every 1 Day)		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Aleve	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Oral	5 Milligram, Bid	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Hcq	C		Unk	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
Insulin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	11912599	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-093211		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone Acetate			S				Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Xeljanz			S	Oral	50 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Oral	5.0 Milligram, Bid		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Folic Acid			C	Subcutaneous	Unk		Not Reported

Folic Acid	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid		Not Reported
Insulin	C	Oral	Unk		Not Reported
Celebrex	C	Unknown	2 Dosage Form, Qd		Not Reported
Acetaminophen And Codeine	C	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	2.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	12694993	EXPEDITED (15-DAY)		OT	CA-SA-2016SA144144			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Plaquenil Sulfate			S	Unknown	200 Mg,Bid		Sanofi
	Arava			S	Unknown	10 Mg,Qd		Sanofi
	Arava			S	Unknown	20 Mg,Qd		Sanofi
	Arava			S	Unknown	10 Mg,Qd		Sanofi
	Methotrexate Sodium			S	Oral	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Kineret			S	Unknown	Unk Unk,Unk		Not Reported
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	13057811	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0494			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Humira	S	Unknown	Dosage: 2x/Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Cyclical	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported

Meloxicam	C	Oral	As Necessary		Not Reported
Meloxicam	C	Oral			Not Reported
Meloxicam	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported
Prednisolone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	13946397	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017455		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	14689574	EXPEDITED (15-DAY)		OT	IE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007426		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective; Intentional Product Use Issue; Leukopenia; Skin Atrophy	Triamcinolone Acetonide			S	Unknown	Unk		Bristol Myers Squibb
	Clobetasol Propionate			S	Topical			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Prednisolone			S	Oral			Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Protopic			S	Topical			Not Reported
	Fluconazole			C	Unknown			Not Reported
	Co-Trimoxazole [Sulfamethoxazole;Trimethoprim]			C	Unknown			Not Reported
	Efavirenz			C	Unknown			Not Reported
	Lamivudine + Zidovudine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	14836032	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1328		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	2x/Week		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Leflunomide	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Rituximab	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Desoximetasone	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	14995535	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268180			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Stomatitis; Therapeutic Product Effect Decreased;	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Plaquenil			S	Oral	400 Mg, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg,Qw		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Actemra			S	Unknown	Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qcy		Not Reported

Weight Decreased	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Valtrex	C	Oral	1000 Mg, Bid	Not Reported
	Esomeprazole Magnesium;Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Rosuvastatin Calcium	C	Oral	1 Df, Qd	Not Reported
	Acetaminophen W/Oxycodone	C	Oral	1 Df, Q4h	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported
	Naproxen	C			Not Reported
	Oxycodone Hydrochloride	C			Not Reported
	Prednisone	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	15568779	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1419		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Finger Deformity; No Adverse Event; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Naproxen	C	Unknown	Not Reported
Atorvastatin Calcium	C	Unknown	Not Reported
Bisoprolol	C	Unknown	Not Reported
Digoxin	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Nifedipine	C	Unknown	Not Reported
Palafer	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Toloxin	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Xarelto	C	Unknown	Not Reported
Zinc Citrate	C	Unknown	Not Reported

	Hydrochlorothiazide	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Atorvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	15605754	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3228		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Endocervical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	15697669	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-17P-028-1856583-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	15719055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017212234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis	Enbrel	S	Unknown	25 Mg, 2 Times/Wk	Unknown
	Sulfasalazine	S		Unk	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Remicade	S	Unknown	300 Mg, Q6wk	Not Reported
	Rituxan	S	Unknown	2000 Mg, 1 Every 6 Months	Not Reported
	Rituxan	S	Unknown	1000 Mg, Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	2000 Mg, Unk (1000 Mg, 2 Doses Every 6 Months)	Not Reported
	Rituximab	S	Unknown	1000 Mg, Every 12 Weeks	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram Per Cubic Metre	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	10 Mg, Qwk	Not Reported
	Gold	C	Intramuscular	50 Mg, Qwk	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	15740714	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015222530		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Enbrel			S		50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Taken For X-Years)		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		25 Mg, Weekly		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		25 G, Weekly		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S		Unk		Not Reported
Orencia	S		Unk		Not Reported
Orencia	S				Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S		Unk		Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk		Not Reported
Gold	S		Unk		Not Reported
Myochrysine	S	Intramuscular	Unk		Not Reported
Hydroxychloroquine Sulfate	S		Unk		Not Reported
Apo-Hydroxyquine	S		Unk		Not Reported
Apo-Leflunomide	S		25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	15781901	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017013508		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S		25 Mg, 2x/Week		Unknown
	Enbrel			S		25 Mg		Unknown
	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Unknown
	Etanercept			S	Subcutaneous	25 Milligram, 2 Times/Wk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported

Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic (Every 2 Weeks)	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic (1 Every 2 Weeks)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Remicade	S	Unknown	300 Mg, Cyclic (Every 6 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Cyclic (1 Every 6 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
Plaquenil	S		200 Mg, 2x/Day	Not Reported
Orencia	S		Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S		Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S		200 Mg, Bid	Not Reported
Apo-Hydroxyquine	S		200 Mg, Bid	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Arava	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk (1 Grams)		Not Reported
Azathioprine	S	Unknown	Unk		Not Reported
Azathioprine	S	Oral	Unk		Not Reported
Gold	S	Intramuscular	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Sulfasalazine	C		1 G, 2x/Day		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	16199338	EXPEDITED (15-DAY)		OT	CA-009507513-1904CAN006094		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Pain; Musculoskeletal Stiffness;	Fosamax			S	Unknown	Unk		Merck
	Fosamax			S	Oral	Unk		Merck
	Acetaminophen (+) Oxycodone Hydrochloride			S	Oral	Unk		Not Reported
	Alendronic Acid			S	Oral	Unk		Not Reported
	Alendronic Acid			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Oral	75.0 Milligram, 1 Every 1 Day		Not Reported
	Amitriptyline Hydrochloride			S	Oral	75.0 Milligram, 1 Every 1 Day		Not Reported
	Amitriptyline Hydrochloride			S		75 Milligram, 1 Every 1 Days		Not Reported
	Amitriptyline Pamoate			S	Oral	75.0 Milligram, 1 Every 1 Day (S)		Not Reported
	Amitriptyline Pamoate			S	Oral	75 Milligram, 1 Every 24 Hours		Not Reported
	Apo-Alendronate			S	Unknown	Unk		Not Reported

Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Skin Ulcer; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Apo Amitriptyline	S	Oral	75 Milligram, 1 Every 24 Hours (1 Day)	Not Reported
	Apo-Meloxicam	S	Unknown	150 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo-Meloxicam	S	Unknown	150 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	250 Milligram, 2 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	1000.0 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 1 Every 24 Hours	Not Reported
	Apo Naproxen	S	Oral	250 Milligram 1 Every 12 Hours	Not Reported
	Apo Naproxen	S	Oral	1000.0 Milligram 1 Every 24 H	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
	Apo Prednisone	S	Oral	15 Milligram, 1 Every 1 Day	Not Reported
	Apo Prednisone	S	Unknown	Unk	Not Reported
	Apo Ranitidine	S	Oral	300 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Ranitidine	S	Oral	150 Milligram, 2 Every 1 Day (S)	Not Reported
	Apo Ranitidine	S	Unknown	Unk	Not Reported

Apo Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 1 Week	Not Reported
Apo Ranitidine	S	Oral	150 Milligram 1 Every 12 Hours	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Azathioprine	S	Unknown	150 Milligram	Not Reported
Azathioprine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	150 Milligram	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Depo-Medrol	S	Intra-articular	Suspension Intra-Articular	Not Reported
Depo-Medrol	S	Unknown	Suspension Intra-Articular	Not Reported
Elavil Pamoate	S	Oral	75 Milligram, 1 Every 1 Days	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Weeks	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every Weeks	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Weeks	Not Reported
Esomeprazole Magnesium (+) Naproxen	S	Oral	Unk	Not Reported
Esomeprazole Magnesium (+) Naproxen	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium (+)	S	Unknown	Unk	Not Reported

Naproxen				
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Oral	Unk	Not Reported
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Oral	Unk	Not Reported
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Oral	Unk	Not Reported
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Oral	Unk	Not Reported
Esomeprazole Magnesium	S	Oral	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	50 Milligram	Not Reported
Humira	S	Subcutaneous	40.0 Milligram, 1 Every 1 Days, Dosage Form: Solution Subcutaneous	Not Reported
Humira	S	Subcutaneous	40 Milligram; Dosage Form: Solution For Injection	Not Reported
Humira	S	Subcutaneous	40 Milligram; Dosage Form: Solution For Injection	Not Reported
Imuran (Azathioprine Sodium)	S	Unknown	150.0 Milligram	Not Reported
Imuran (Azathioprine Sodium)	S	Unknown	150.0 Microgram	Not Reported
Lyrica	S	Oral	150 Milligram, 2 Every 1 Day(S)	Not Reported
Lyrica	S	Oral	300 Milligram, 1 Every 1	Not Reported

			Days	
Lyrica	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Meloxicam	S	Unknown	150 Milligram, 1 Every 1 Days	Not Reported
Meloxicam	S	Unknown	Unk	Not Reported
Meloxicam	S	Unknown	150 Milligram, 1 Every 24 Hours	Not Reported
Meloxicam	S	Unknown	Unk	Not Reported
Meloxicam	S	Unknown	Unk	Not Reported
Meloxicam	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	20 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported

Methotrexate	S		Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Methylprednisolone Sodium Succinate	S	Intra-articular	Unk	Not Reported
Methylprednisolone Sodium Succinate	S	Unknown	Unk	Not Reported
Methylprednisolone Acetate	S	Intra-articular	Unk	Not Reported
Methylprednisolone Acetate	S	Unknown	Unk	Not Reported
Mobicox	S	Oral	Unk	Not Reported
Mobicox	S	Unknown	Unk	Not Reported
Mobicox	S	Oral	150 Milligram, 1 Every 1 Days	Not Reported
Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
Naproxen	S	Oral	500 Milligram, 1 Every 1 Days	Not Reported
Naproxen	S	Oral	250 Milligram, 2 Every 1 Days	Not Reported
Naproxen	S	Oral	1000 Milligram, 2 Every 1 Days	Not Reported
Naproxen	S	Oral	1000 Milligram, 1 Every 1 Days	Not Reported
Naproxen	S	Oral	Unk	Not Reported
Naproxen	S	Oral	500 Milligram, 2 Every 1 Days, Tablet (Enteric Coated)	Not Reported
Naproxen	S	Oral	250 Milligram, 2 Every 1 Days, Tablet (Enteric Coated)	Not Reported
Naproxen	S	Oral	500 Milligram, 1 Every 1 Days	Not Reported
Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported

Naproxen	S	Oral	1000 Milligram, 1 Every 1 Days	Not Reported
Naproxen	S	Oral	1 Every 1 Days	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S	Oral	250 Milligram, 1 Every 12 Hours	Not Reported
Naproxen	S	Oral	1000 Milligram, 1 Every 1 Days	Not Reported
Oxycocet	S	Unknown	Unk	Not Reported
Oxycocet	S	Oral	Unk	Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Pantoloc	S	Oral	Dosage Form: Tablet (Enteric Coated), Every 1 Day	Not Reported
Pantoloc	S	Unknown	Unk	Not Reported
Pantoloc	S	Oral	Unk	Not Reported
Pantoloc	S	Oral	Every 1 Days	Not Reported
Pantoprazole	S	Oral	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pantoprazole	S	Oral	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pantoprazole	S	Oral	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pantoprazole	S	Oral	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	S	Oral	Unk, 1 Every 1 Days	Not Reported
Pantoprazole Sodium	S	Oral	Unk Unk, 1 Every 1 Days	Not Reported
Prednisone	S	Unknown	15.0 Milligram, 1 Every 1 Day	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported

Prednisone	S	Unknown	15 Milligram, 1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	150 Milligram, 1 Evey 1 Days, Dosage Form: Not Specified	Not Reported
Pregabalin	S	Oral	300 Milligram, 1 Every 1 Day(S)	Not Reported
Pregabalin	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Pregabalin	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Pregabalin	S	Oral	150 Milligram, 1 Every 1 Days	Not Reported
Pregabalin	S	Unknown	150 Milligram, 1 Every 12 Hours	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 1 Day	Not Reported
Ranitidine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 1 Week	Not Reported
Ranitidine	S	Unknown	Unk	Not Reported
Ranitidine Hydrochloride	S	Oral	300 Milligram, 1 Every 1 Days	Not Reported
Ratio Oxycocet	S	Unknown	Unk	Not Reported
Ratio Oxycocet	S	Oral	1 Every 1 Weeks	Not Reported
Septra	S	Unknown	Unk	Not Reported
Sulfamethoxazole (+) Trimethoprim	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Day(S), Dosage Form: Not Specified	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Days	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, 1 Every 1	Not Reported

			Week	
Sulfasalazine	S	Oral	1 Gram, 1 Every 24 Hours	Not Reported
Tofacitinib Citrate	S	Oral	10 Milligram, 1 Every 1 Day(S)	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, 2 Every 1 Days	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, 1 Every 24 Hours	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, 1 Every 24 Hours	Not Reported
Trimethoprim	S	Unknown		Not Reported
Vimovo	S	Unknown	Tablet (Delayed And Immediate Release)	Not Reported
Vimovo	S	Oral	Unk	Not Reported
Vimovo	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	10 Milligram, 1 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	2 Dosage Form, 1 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	2 Milligram, 1 Every 1 Days	Not Reported
Xeljanz	S	Oral	2 Milligram, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	10 Milligram, 1 Every 24 Hours	Not Reported
Xeljanz	S	Oral	5 Milligram, 1 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	5 Milligram 1 Every 12 Hours	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Dosage Form: Not Specified	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Plaquenil	C		Unk	Not Reported
Cannabis Sativa	C	Unknown	1.0 Gram, 1 Every 1 Days	Not Reported
Cimzia	C	Unknown		Not Reported
Codeine	C			Not Reported
Eltroxin	C		175 Milligram, 1 Every 1 Days	Not Reported
Orencia	C	Subcutaneous	125.0 Milligram, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	16347402	EXPEDITED (15-DAY)		OT	CA-SA-2019SA139156			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Sarilumab			S	Subcutaneous	20 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd (1 Every 1 Day)		Sanofi
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw (1 Every 1 Week)		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			S		Unk		Not Reported
	Nicotinamide			S		Unk		Not Reported

Thiamine Hydrochloride	S		Unk	Not Reported
Esomeprazole Sodium	S		Unk	Not Reported
Folic Acid	S		Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Actemra	S	Subcutaneous	162 Mg, Qw	Not Reported
Azathioprine	S		Unk	Not Reported
Ciclosporin	S			Not Reported
Enbrel	S		Unk	Not Reported
Adalimumab	C		Unk	Not Reported
Ergocalciferol	C		Unk	Not Reported
Hydroxychloroquine	C		Unk	Not Reported
Metformin	C		Unk	Not Reported
Nexium [Esomeprazole Sodium]	C		Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Magnesium	C		Unk	Not Reported
Sodium Aurothiomalate	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Dexpanthenol	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Nexium [Esomeprazole Magnesium]	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	16413232	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044080		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unknown		Not Reported

Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Kevzara	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	16439513	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-14998		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-	Etanercept			S	Subcutaneous			Not Reported

Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Etanercept	S	Unknown	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S			Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Unknown. Solution	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S			Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported

Rituximab	S	Intravenous drip			Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Sulfasalazine	S				Not Reported
Tocilizumab	S	Unknown	Unknown		Not Reported
Tocilizumab	S				Not Reported
Tocilizumab	S				Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S				Not Reported
Actemra	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17164952	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019538925		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Prescribed; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Papilloedema; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S		Unk		Unknown
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		8 Mg/Kg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Leflunomide			S		10 Mg, 1x/Day		Not Reported
	Leflunomide			S	Subcutaneous	Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

	Naproxen Sodium	S		Unk	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Celebrex	C		Unk	Not Reported
	Plaquenil Sulfate	C	Oral	200 Mg, 2x/Day	Not Reported
	Folic Acid	C		Unk	Not Reported
	Hydroxychloroquine Sulfate	C		300 Mg, 1x/Day (Qd)	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Mg, 1x/Day (Qd)	Not Reported
	Hydroxychloroquine Sulfate	C	Subcutaneous	40 Mg	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Xeljanz	C	Oral	5 Mg	Not Reported
	Methotrexate	C		20 Mg, Weekly	Not Reported
	Methotrexate	C	Oral	Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg	Not Reported
	Methotrexate	C		15 Mg	Not Reported
	Methotrexate	C		10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17310605	EXPEDITED (15-DAY)		OT	CA-009507513-2001CAN007489		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Blood Cholesterol Increased; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache;	Fosamax			S	Oral	Unk		Merck
	Fosamax			S	Unknown	Unk		Merck
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution For Injection In Pre-Filled Pen		Merck
	Simponi			S	Subcutaneous	Unk		Merck
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Hypersensitivity; Hypertension; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Apo Prednisone	S	Unknown	Unk	Not Reported
	Apo Prednisone	S			Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram, Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram; Solution For Injection In Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Folic Acid	S	Unknown	5.0 Milligram, Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Formulation: Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported

Methotrexate	S	Oral	25 Milligram 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	20 Milligram, 1 Every 1 Days	Not Reported
Methotrexate	S	Unknown	20 Milligram, 1 Every 1 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Plaquenil	S	Unknown	400.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Plaquenil	S	Unknown	400 Milligram, Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
Reactine (Cetirizine Hydrochloride)	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1000.0 Milligram, Bid (2	Not Reported

				Every 1 Day)	
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk, 2 Every 1 Days	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown	50 Milligram, Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S			Not Reported
	Apo Folic Acid	S	Unknown	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S			Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Unknown		Not Reported
	Diclofenac	C	Unknown	50 Milligram	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17760562	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020183153			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Pneumonitis; Psoriasis;	Infliximab			S	Unknown	Unk		Unknown

Urticaria	Levofloxacin	S	Unknown	Unk		Pfizer
	Methylprednisolone Acetate	S	Unknown	Unk		Pfizer
	Leflunomide	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17798648	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123042			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Arava			S	Unknown	10 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S	Unknown	10 Mg, Qd		Sanofi
	Plaquenil Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17823096	EXPEDITED (15-DAY)		HO, OT	NVSC2020US120186		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Decreased Appetite; Ejection Fraction Decreased; Fatigue; Memory Impairment; Seizure	Trametinib			S	Oral	30 Mg		Novartis
	Trametinib			S	Oral	27 Mg		Novartis
	Trametinib			S	Oral	39 Mg		Novartis
	Trametinib			S	Oral	Unk		Novartis

Comparator Hydroxychloroquine Sulfate	S	Oral	1000 Mg		Not Reported
Comparator Hydroxychloroquine Sulfate	S	Oral	8750 Mg		Not Reported
Comparator Hydroxychloroquine Sulfate	S	Oral	11475 Mg		Not Reported
Comparator Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Bevacizumab	C	Unknown	Unk		Not Reported
Bevacizumab	C	Unknown	Unk		Not Reported
Dexamethasone	C	Unknown	1 Mg		Not Reported
Megestrol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17843009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606641			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Folic Acid	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Fosamax	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17843654	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17855942	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

	Bupropion	C	Not Reported
	Sulfasalazine	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17856967	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18019458	EXPEDITED (15-DAY)		HO	CA-ACCORD-189780		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue;	Gabapentin			S	Oral	1 Every 2 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Fentanyl			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Myochrysine			S	Intramuscular	Intramuscular Solution, 1 Every 3 Weeks		Not Reported

Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Oxycontin	S	Unknown	1 Every 1 Months	Not Reported
	Sulfasalazine	S	Unknown	1 Every 1 Days	Not Reported
	Prednisone	C			Not Reported
	Trazodone	C			Not Reported
	Tylenol	C			Not Reported
	Zoledronic Acid	C			Not Reported
	Nasonex	C		Spray, Metered Dose	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Orencia	S	Subcutaneous	1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18053363	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007233			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Osteonecrosis; Pain; Pain In Extremity; Peripheral Swelling; Rebound Effect	Hydroxychloroquine			S	Oral	Unk		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Concordia
	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	10 Mg		Not Reported
	Prednisone			S	Oral	40 Mg, Increase Prednisone To 40 Mg And Start A Weekly Taper		Not Reported
	Prednisone			S	Oral	10 Mg, Tapered		Not Reported

Prednisone	S	Oral	40 Mg, Qd, Increase Prednisone Again To 40 Mg And Start A Weekly Taper		Not Reported
Prednisone	S	Oral	10 Mg, Weekly,Weekly Taper Back To 10 Mg		Not Reported
Azathioprine	C		Unk		Not Reported
Azathioprine	C	Unknown	100 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18059147	EXPEDITED (15-DAY)		HO, OT	NL-MYLANLABS-2020M1051866		57 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Etanercept			S	Subcutaneous	1 Dosage Form, Qw		Not Reported
	Etanercept			S		Unk		Not Reported
	Sulfasalazine			S	Oral	2 Dosage Form (2 Df,Unk; Tablets)		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S	Oral	1 Dosage Form, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Plaquenil /00072603/			S	Oral	1 Dosage Form, Qd		Mylan
	Hydroxychloroquine Sulfate			S		Unk		Mylan
	Bisoprolol			C	Oral	10 Milligram, Qd		Mylan
	Lisinopril			C	Oral	10 Milligram, Qd		Mylan
	Pantoprazole			C	Oral	40 Milligram, Qd		Mylan
	Hydrochlorothiazide With Triamterene			C	Oral	Unk (1 Dd 1 Stuk(S), Extra Info: 50/4)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18068682	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014354126		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Anaemia; Angioedema; Asthenia; Blister; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Feeling Abnormal; Feeling Drunk; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Hypoaesthesia; Inappropriate Schedule Of Product Administration; Migraine; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Pharyngeal Swelling; Psoriatic Arthropathy; Pyrexia; Swelling Face; Synovitis; Uveitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Enbrel			S		Unk		Unknown
	Methotrexate Sodium			S		15 Mg		Pfizer
	Methotrexate Sodium			S		20 Mg		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		12.5 Mg		Pfizer
	Arthrotec			S		75 Mg, 2x/Day		Pfizer
	Lipitor			S	Oral	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Abbott
	Humira			S	Subcutaneous	Unk		Abbott
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Dovobet			C	Topical	Unk		Not Reported
	Omeprazole			C	Oral	Unk		Not Reported
	Vitamin D2			C	Oral	1000 Df		Not Reported
	Flovent			C		Unk		Not Reported
	Folic Acid			C	Oral	Unk		Not Reported
	Multi Vitamin & Mineral			C	Oral	Unk		Not Reported
	Ventolin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18070322	NON-EXPEDITED			US-ADVANZ PHARMA-202007007342			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lactose Intolerance; Product Formulation Issue	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18089279	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-255441		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury; Off Label Use	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Ranbaxy
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Lopinavir/Ritonavir			S	Unknown	400/100 Mg, Bid		Not Reported
	Paracetamol			S	Unknown	Unk		Ohm Lab
	Teicoplanin			C	Intravenous (not otherwise specified)	400 Milligram, Daily		Not Reported
	Piperacillin-Tazobactam			C	Unknown	4.5 Gram, Tid		Not Reported
	Enoxaparin			C	Subcutaneous	4000 International Unit, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18089299	NON-EXPEDITED		HO	US-STRIDES ARCOLAB LIMITED-2019SP005622		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Asthenia; Chills; Cough; Decreased Appetite; Fatigue; Hypercalcaemia; Lymphoproliferative Disorder; Off Label Use;	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Strides
	Mycophenolate Mofetil			S				Strides
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg Weekly, Unk		Not Reported

Pancytopenia; Pyrexia; Weight Decreased	Hydroxychloroquine		S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18089301	NON-EXPEDITED		HO, LT, OT	US-STRIDES ARCOLAB LIMITED-2019SP005786		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brudzinski'S Sign; Chills; Dehydration; Depressed Level Of Consciousness; Diarrhoea; Encephalitis; Fatigue; Gastroenteritis; Headache; Lethargy; Malaise; Meningism; Mental Status Changes; Mucosal Dryness; Myalgia; Nausea; Off Label Use; Pyrexia; Tachycardia; Vomiting; West Nile Viral Infection	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	6 Mg/Day Part Of A Regimen That Involved Tapering Of The Dose		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfamethoxazole And Trimethoprim			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18089387	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007393			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	300mg 5 Days Weekly + 200mg 2 Days Weekly		Concordia
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	Decreasing Dose		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18089703	EXPEDITED (15-DAY)		HO, OT	BR-LUPIN PHARMACEUTICALS INC.-2020-04072		29 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Exposure During Pregnancy; Off Label Use; Premature Delivery	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	12 Milligram, Qd		Lupin
	Methyldopa			S	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18089845	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-03834		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury; Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Lopinavir/Ritonavir			S	Unknown	Unk Unk, Bid (400/100 Mg)		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18089993	EXPEDITED (15-DAY)		HO, OT	IE-LUPIN PHARMACEUTICALS INC.-2020-03867		22 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Doxycycline			S	Unknown	Unk		Lupin
	Doxycycline			S				Lupin
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Pembrolizumab			C	Unknown	400 Milligram (Received Six Cycles; Patient Was Due For Seventh Cycle)		Not Reported
	Adriamycin [Doxorubicin]			C	Unknown	Unk (Received Two		Not Reported

			Cycles Of Abvd Regimen And Four Cycles Of Escbeacopp Regimen)	
Bleomycin	C	Unknown	Unk(Received Two Cycles Of Abvd Regimen And Four Cycles Of Escbeacopp Regimen)	Not Reported
Vinblastine	C	Unknown	Unk (Received Two Cycles Of Abvd Regimen)	Not Reported
Dacarbazine	C	Unknown	Unk (Received Two Cycles Of Abvd Regimen)	Not Reported
Etoposide	C	Unknown	Unk (Received Four Cycles Of Escbeacopp Regimen)	Not Reported
Etoposide	C	Unknown	Received Three Cycles Of Ice Regimen	Not Reported
Doxorubicin	C	Unknown	Unk	Not Reported
Cyclophosphamide	C	Unknown	Unk (Received Four Cycles Of Escbeacopp Regimen)	Not Reported
Vincristine	C	Unknown	Unk (Received Four Cycles Of Escbeacopp Regimen)	Not Reported
Procarbazine	C	Unknown	Unk (Received Four Cycles Of Escbeacopp Regimen)	Not Reported
Prednisolone	C	Unknown	Unk (Received Four Cycles Of Escbeacopp Regimen)	Not Reported
Ifosfamide	C	Unknown	Unk (Received Three Cycles Of Ice Regimen)	Not Reported
Carboplatin	C	Unknown	Unk (Received Three Cycles Of Ice Regimen)	Not Reported
Brentuximab Vedotin	C	Unknown	Unk (Received Three Cycles)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090125	EXPEDITED (15-DAY)		OT	CA-ACCORD-192867		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090127	EXPEDITED (15-DAY)		HO	NL-ACCORD-193034		57 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Methotrexate			S		1 Time Per Week 1 Piece(S), Extra Info: 25 Mg/Wk		Accord
	Sulfasalazine			S		2 Times Per Day 4 Piece (S), Extra Info: 500 Mg		Not Reported
	Etanercept			S		1 Time Per Week 1 Piece (S), Extra Info: 50 Mg		Not Reported
	Plaquenil			S		1 Time Per Day 1 Piece(S), Extra Info: 200 Mg		Not Reported
	Bisoprolol			C		1 Time Per Day 1 Piece (S), Extra Info: 10 Mg		Not Reported
	Lisinopril			C		1 Time Per Day 1 Piece (S), Extra Info: 10 Mg		Not Reported

	Hydrochlorothiazide/Triamterene	C	1 Time Per Day 1 Piece(S), Extra Info: 50/4	Not Reported
	Pantozol	C	1 Time Per Day 1 Piece(S), Extra Info: 40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090128	EXPEDITED (15-DAY)		OT	CA-ACCORD-192920		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Xeljanz			C	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090145	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806969		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate	S	Intravenous (not otherwise specified)	Barr
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine/00072603/	S	Oral	Not Reported
	Hydroxychloroquine/00072603/	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090158	EXPEDITED (15-DAY)		OT	CA-ACCORD-193112			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090173	EXPEDITED (15-DAY)		OT	IQ-LUPIN PHARMACEUTICALS		46 YR	Male	IRQ

INC.-2020-03916

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Enoxaparin			C	Unknown	4000 International Unit, Qd		Not Reported
	Kaletra			C	Unknown	1 Dosage Form, Unk (800/200 Mg)		Not Reported
	Meropenem			C	Unknown	1 Gram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090243	EXPEDITED (15-DAY)		HO, OT	BR-LUPIN PHARMACEUTICALS INC.-2020-03822		44 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Fentanyl			S	Unknown	Unk		Not Reported
	Noradrenaline [Norepinephrine Bitartrate]			S	Unknown	Unk		Not Reported
	Noradrenaline [Norepinephrine Bitartrate]			S	Unknown	Unk (Dose Increased)		Not Reported
	Midazolam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090272	EXPEDITED (15-DAY)		HO, OT	BR-LUPIN PHARMACEUTICALS INC.-2020-04066			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin	S	Transplacental	Unk	Lupin
	Ceftriaxone	S	Transplacental	Unk	Lupin
	Ceftriaxone	S			Lupin
	Oseltamivir	S	Transplacental	Unk	Lupin
	Hydroxychloroquine	S	Transplacental	Unk	Lupin
	Fentanyl	S	Transplacental	Unk	Not Reported
	Noradrenaline [Norepinephrine Bitartrate]	S	Transplacental	Unk	Not Reported
	Noradrenaline [Norepinephrine Bitartrate]	S	Transplacental	Unk (Dose Increased)	Not Reported
	Midazolam	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090317	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-192694		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Warfarin			S				Not Reported
	Amitriptyline			C				Not Reported
	Warfarin			S				Not Reported
	Rituximab			S		Solution For Infusion		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S		Accord
	Hydroxychloroquine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090438	EXPEDITED (15-DAY)		OT	IQ-LUPIN PHARMACEUTICALS INC.-2020-03915		56 YR	Male	IRQ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate Tablets			S	Unknown	400 Milligram, Bid (On First Day)		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Unknown	200 Milligram, Bid		Lupin
	Oseltamivir			S	Unknown	75 Milligram, Bid		Lupin
	Meropenem			C	Unknown	1 Gram, Tid		Not Reported
	Kaletra			C	Unknown	1 Dosage Form, Bid		Not Reported
	Enoxaparin			C	Subcutaneous	4000 International Unit, Qd		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090440	EXPEDITED (15-DAY)		OT	PE-LUPIN PHARMACEUTICALS INC.-2020-03832		41 YR	Female	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Exposure During Pregnancy; Off Label Use; Premature Delivery; Respiratory Failure	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Meropenem			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090442	EXPEDITED (15-DAY)		LT, OT	PE-LUPIN PHARMACEUTICALS INC.-2020-03869			Male	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Vancomycin			S	Transplacental	Unk		Lupin
	Oseltamivir			S	Transplacental	Unk		Lupin
	Meropenem			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090452	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1806396		84 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis; Covid-19 Treatment; Hepatocellular Injury	Hydroxychloroquine			S	Oral	400mg 12 / 12h In D0 And Then 200mg 12 / 12h		Teva
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Sertraline			C	Oral	50 Mg		Not Reported
	Oxazepam			C	Oral	15 Mg		Not Reported
	Omeprazole			C	Oral	20 Mg		Not Reported
	Ketorolac			C	Intravenous (not otherwise specified)	Sos 2, Unit Dose: 30 Mg		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	3000 Mg		Not Reported
	Piperacillin, Tazobactam			C	Intravenous (not otherwise specified)	9000 Mg		Not Reported
	Nifedipine			C	Oral	60 Mg		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	120 Mg		Not Reported
	Quetiapine			C	Oral	25 Mg		Not Reported
	Captopril			C	Oral	Sos 3, 25 Mg		Not Reported
	Indapamide			C	Oral	2.5 Mg		Not Reported

Candesartan	C	Oral	32 Mg		Not Reported
Morphine	C		Sos 4, 2 Mg, Parenteral		Not Reported
Cefazolin	C	Intravenous (not otherwise specified)	3000 Mg		Not Reported
Amiodarone	C	Oral	200 Mg		Not Reported
Nolotil	C	Intravenous (not otherwise specified)	4000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090455	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1805895		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Leukopenia; Neutropenia; Off Label Use	Cyclosporine A			S	Unknown			Ivax
	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone			S	Oral	Unknown Dose		Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Tocilizumab			S	Subcutaneous	Received Single Dose		Not Reported
	Meropenem			C	Unknown			Not Reported
	Intravenous Immunoglobulins			C	Intravenous (not otherwise specified)	0.3 G/Kg		Not Reported
	Azithromycin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090478	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-03785		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	250 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Tid		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090490	NON-EXPEDITED		HO	US-STRIDES ARCOLAB LIMITED-2019SP008144		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Disease Progression; Mycobacterial Infection; Off Label Use; Osteomyelitis; Subcutaneous Abscess	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090532	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-03824		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Stress Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Endocervical	30 Milligram, Unk (Dose Reduced)		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk (Dose Was Reduced By 50 Percent)		Not Reported
	Mycophenolate			S	Unknown	Unk (Resumed)		Not Reported
	Epoprostenol			S	Unknown	Unk		Not Reported
	Basiliximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090849	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-03932		50 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S	Oral	400 Milligram, Bid	Lupin
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Lupin
	Thymoglobulin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk, On Demand	Not Reported
	Losartan	C	Unknown	50 Milligram	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Meropenem	C	Unknown	Unk	Not Reported
	Lopinavir/Ritonavir	C	Oral	400/100, Bid	Not Reported
	Everolimus	C	Unknown	Unk	Not Reported
	Ceftaroline	C	Unknown	Unk	Not Reported
	Tacrolimus	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090880	EXPEDITED (15-DAY)		OT	CA-ACCORD-192869		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Estrogel			C	Unknown	3 Every 1 Days		Not Reported
	Ergocalciferol			C	Unknown	1 Every 1 Weeks		Not Reported
	Furosemide			C	Unknown	1 Every 1 Days		Not Reported
	Morphine			C	Unknown			Not Reported
	Dorzolamide/Timolol			C	Unknown	2 Every 1 Days		Not Reported
	Potassium			C	Unknown	1 Every 1 Days		Not Reported
	Valsartan			C	Unknown	1 Every 1 Days		Not Reported

	Xalatan	C	Ophthalmic	1 Every 1 Days	Not Reported
	Zingiber Officinale/Zingiber Officinale Rhizome	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090883	EXPEDITED (15-DAY)		OT	CA-ACCORD-192886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S		1 Every 1 Days		Accord
	Actemra			S				Not Reported
	Leflunomide			S				Not Reported
	Enbrel			S				Not Reported
	Aurothioglucose			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090885	EXPEDITED (15-DAY)		OT	CA-ACCORD-193370		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine	S			Not Reported
	Xeljanz	C	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090900	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-193374		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Viral Infection	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Actemra			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Enbrel			S				Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz			C				Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18090919	EXPEDITED (15-DAY)		OT	CA-ACCORD-192893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Accord
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Orencia	S	Intravenous drip		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone/Prednisone Acetate	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Cortisone	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18091144	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2019SP008397		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Mycophenolate Mofetil			S	Oral	Unk		Strides
	Prednisolone			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18091307	EXPEDITED (15-DAY)		OT	CA-ACCORD-193133		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Methotrexate			S	Oral	Frequency: 1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Oral	Frequency: 1 Every 1 Days		Not Reported
	Leflunomide			S				Not Reported
	Otezla			S		Frequency: 2 Every 1 Days		Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C		Frequency: 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18091704	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001133			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Anxiety; Arthralgia; Arthritis; Arthritis; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Apo-Hydroxyquine		Concordia
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Unknown	10 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Unknown	9 Mg, Qd		Not Reported
	Prednisone			S	Unknown	9 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg		Not Reported
	Rituxan			S	Intravenous (not	1000 Mg Qcy		Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	9 Mg	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Cortisone	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported
	Desoximetasone	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Gabapentine	C		Unk	Not Reported
	Reactine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092060	EXPEDITED (15-DAY)		OT	CA-ACCORD-192810			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pancytopenia; Rash	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S		Frequency: 2 Every 1 Days		Not Reported
	Prednisone			C				Not Reported
	Asaphen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092061	EXPEDITED (15-DAY)		OT	CA-ACCORD-192495		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective;	Methotrexate			S				Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not			Not Reported

Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis				otherwise specified)			
	Hydroxychloroquine		S				Not Reported
	Humira		S	Subcutaneous			Not Reported
	Folic Acid		S				Not Reported
	Enbrel		S	Subcutaneous			Not Reported
	Prednisone		S				Not Reported
	Naproxen		S				Not Reported
	Leflunomide		S	Oral	2 Every 1 Days		Not Reported
	Adalimumab		S	Subcutaneous			Not Reported
	Actemra		S				Not Reported
	Hydroxychloroquine		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092083	EXPEDITED (15-DAY)		OT	CA-ACCORD-192851			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate			S		1 Every 1 Weeks		Accord
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Tofacitinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092087	EXPEDITED (15-DAY)		OT	CA-ACCORD-192863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug	Methotrexate			S	Unknown			Accord
	Arava			S	Unknown			Not Reported

Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous	Not Reported
	Cosentyx	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Otezla	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092089	EXPEDITED (15-DAY)		OT	CA-ACCORD-193137		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Apo-Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092090	EXPEDITED (15-DAY)		OT	CA-ACCORD-193269		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092160	EXPEDITED (15-DAY)		DE, HO	ES-BAYER-2020-148399		72 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug-Induced Liver Injury; Electrocardiogram Qt Prolonged	Interferon Beta - 1b			S	Subcutaneous	Unk		Bayer
	Azithromycin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Lopinavir + Ritonavir			S		Unk		Not Reported
	Ceftriaxone			S		Unk		Not Reported
	Metilprednisolona Normon 20mg Polvo Y Disolvente Para Solucion Inyecta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092215	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-059893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Celebrex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092231	EXPEDITED (15-DAY)		OT	CA-ACCORD-193378		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Methotrexate			S		1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092237	EXPEDITED (15-DAY)		OT	CA-ACCORD-192702		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Weeks		Accord
	Actemra			S				Not Reported
	Arava			S		Frequency: 1 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous, Frequency: 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092238	EXPEDITED (15-DAY)		OT	CA-ACCORD-192695			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	Solution Subcutaneous		Accord
	Actemra			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092241	EXPEDITED (15-DAY)		OT	CA-ACCORD-192993			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported
	Cimzia			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092243	EXPEDITED (15-DAY)		OT	CA-ACCORD-193278		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Oral			Accord
	Apo-Azathioprine			S				Not Reported

	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S			Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Methotrexate		S	Subcutaneous		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092356	EXPEDITED (15-DAY)		HO, OT	GR-SAMSUNG BIOEPIS-SB-2019-00366		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Citalopram			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Prednisolone			S	Unknown	7.5		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Folate			S	Unknown	5 Mg, Qw		Not Reported
	Captopril			S	Unknown	Unknown		Not Reported
	Alprazolam			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Valsartan			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092358	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-23776		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine Sodium			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Parenteral	Unknown		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported
	Tofacitinib			C	Unknown	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092701	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1067995		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heparin-Induced Thrombocytopenia; Off Label Use; Skin Necrosis	Heparin			S		Unk, Qh		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Metoprolol			C	Unknown			Mylan
	Ceftriaxone			C	Unknown	2 Gram		Mylan
	Azithromycin			C	Unknown	500 Milligram		Mylan
	Furosemide			C	Unknown			Mylan
	Cisatracurium			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092833	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182796			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dental Care; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete; Vomiting; Weight Decreased	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Plaquenil			S	Oral	300 Mg,Qd		Sanofi
	Plaquenil			S	Oral	200 Mg,Qd		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S		20 Mg, Qw		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Adalimumab			S	Subcutaneous	Unk Unk,Qow		Not Reported
	Calcium			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Magnesium			C				Not Reported
	Naproxen			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Potassium			C				Not Reported
	Tramadol			C				Not Reported
	Ergocalciferol			C				Not Reported

	Vitamin D [Colecalciferol]			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092891	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1067492		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use; Severe Acute Respiratory Syndrome	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown	9 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported
	Losartan			C	Unknown	25 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092908	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2020122090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral	Unk		Amgen
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092971	EXPEDITED (15-DAY)		OT	GR-LUPIN PHARMACEUTICALS INC.-2020-03871		89 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Azithromycin		S	Unknown	Unk	Lupin
	Hydroxychloroquine		S	Unknown	Unk	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18093006	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019134446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Bupropion			C		Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18093090	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1067627		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heparin-Induced Thrombocytopenia; Off Label Use; Pulmonary Embolism	Heparin			S	Subcutaneous	5000 Units		Not Reported
	Heparin			S	Unknown	18 Units/Kg; Infusion		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Mylan
	Nitric Oxide			S				Mylan
	Ceftriaxone			C	Unknown			Mylan
	Azithromycin			C	Unknown			Mylan
	Remdesivir			C	Unknown			Mylan
	Norepinephrine			C	Unknown			Mylan
	Vasopressin			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18093653	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-061189		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity Pneumonitis; Nasopharyngitis	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Rixathon			S	Unknown	Unk		Not Reported
	Mtx [Methotrexate]			S	Unknown			Not Reported
	Hcq			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18093681	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP014517		11 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence; Drug	Hydromorphone			S	Unknown	Unk		Not Reported

Ineffective; Product Prescribing Error; Respiratory Depression	Lorazepam	S	Sublingual	0.5 Milligram, Prn	Not Reported
	Lorazepam	S	Sublingual	2 Milligram, Prn	Not Reported
	Lorazepam	S			Not Reported
	Clobazam	S	Oral	20 Milligram, Bid	Apotex
	Celecoxib	S	Oral	100 Milligram, Bid	Apotex
	Gabapentin	S	Oral	600 Milligram, Tid	Apotex
	Aripiprazole	S	Oral	2 Milligram, Tid	Apotex
	Baclofen	S	Oral	20 Milligram, Tid	Apotex
	Bisacodyl	S	Oral	5 Milligram, Qd (Prn)	Not Reported
	Clonidine	S	Oral	0.05 Milligram, Q.Am	Apotex
	Clonidine	S	Oral	0.1 Milligram, Every Evening	Apotex
	Dimenhydrinate	S	Oral	25 Milligram, Qd (Prn)	Not Reported
	Diphenhydramine	S	Oral	12.5 Milligram, Q.6h (Prn)	Apotex
	Fluoxetine	S	Oral	20 Milligram, Qd	Apotex
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Apotex
	Ketorolac	S	Oral	20 Milligram, Q.6h (Prn)	Apotex
	Montelukast	S	Oral	10 Milligram, Qd	Apotex
	Pantoprazole	S	Oral	40 Milligram, Qd	Apotex
	Ranitidine	S	Oral	150 Milligram, Qd	Apotex
	Salbutamol	S		100 Microgram, Q.4h.(2 Piffs Prn)	Apotex
	Fluticasone	S		250 Microgram, Qd (2 Puffs)	Apotex
	Ascorbic Acid	S	Oral	1500 Milligram, Qd	Not Reported
	Leuprolide [Leuprorelin]	S	Intramuscular	7.5 Milligram, Q.M.T.	Not Reported
	Melatonin	S	Oral	10 Milligram, Q.H.S. (Prn)	Not Reported
	Methadone	S	Oral	2 Milligram, Tid	Not Reported
	Methocarbamol;Paracetamol	S	Oral	400/500 Mg, Bid	Not Reported
	Phenobarbital	S	Oral	30 Milligram, Bid	Not Reported

	Methocarbamol		S	Unknown	Unk	Not Reported
	Omega 3 Fish Oil [Docosahexaenoic Acid;Eicosapentaenoic Acid]		S	Oral	200-400-1000 Mg, Qd	Not Reported
	Vitamin D3		S	Oral	200 International Unit, Qd	Not Reported
	Polyethylene Glycol [Macrogol]		S	Oral	30 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18094060	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2020SP006018		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Tacrolimus			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Tapering Dose		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18094646	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005470		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	10 Milligram		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Infection; Hepatic Enzyme Increased; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Cimzia	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram (2 Every 1 Day)	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported

	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Salmon Oil	C	Unknown	Unk	Not Reported
	Ativan	C	Unknown	2 Milligram, Prn	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Glucosamine	C	Unknown	Unk	Not Reported
	Lansoprazole	C	Unknown	30 Milligram (2 Every 1 Day)	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Vitamin D [Vitamin D Nos]	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096171	EXPEDITED (15-DAY)		HO, OT	NVSC2020GR211083		60 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hydroxychloroquine			S	Unknown	20 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096325	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-021547		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise;	Metformin Hydrochloride			S	Unknown			Santarus
	Metformin Hydrochloride			S				Santarus
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Warfarin Sodium		S	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Xarelto		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096989	DIRECT		DS			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Product Taste Abnormal	Hydroxychloroquine 200 Mg			S	Oral	Quantity:1 Tablet(S);		Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097407	EXPEDITED (15-DAY)		OT	NVSC2020PT212250		56 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Azithromycin			S	Oral	500 Mg, Qd (Last Administration On 02 Apr 2020)		Novartis
	Plaquinol			S	Oral	400 Mg, Qd (12/12h Em D0 E Depois 200mg 12/12h) (Pneumonia A Sars-Cov-2)		Not Reported
	Flucloxacillin			C	Intravenous (not otherwise specified)	12000 Mg, Qd		Not Reported
	Metamizole Magnesium			C	Intravenous (not otherwise specified)	2000 Mg		Not Reported
	Metamizole Magnesium			C	Oral	575 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2000 Mg, Qd		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	1000 Ml, Qd		Not Reported
	Gentamicin			C	Intravenous (not otherwise specified)	240 Mg, Qd		Not Reported

	Paracetamol		C	Oral	1000 Mg	Not Reported
	Paracetamol		C	Intravenous (not otherwise specified)	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097676	EXPEDITED (15-DAY)		OT	CA-009507513-2007CAN010767			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Fosamax			S	Oral			Merck
	Remicade			S	Intravenous (not otherwise specified)	Powder For Injection		Not Reported
	Simponi			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Merck
	Adalimumab			S	Subcutaneous	40.0 Milligram		Not Reported
	Apo Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous/Solution For Injection		Not Reported
	Cortisone Acetate			S	Topical	25.0 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Dosage Form Not Specified		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1.0 Milligram		Not Reported

	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500.0 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097743	EXPEDITED (15-DAY)		DE, HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254311		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Dexamethasone			S	Unknown	Unk		Sun
	Pomalidomide			S	Unknown	Unk		Not Reported
	Carfilzomib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	11525254	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015308388		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Incomplete; Wound	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Enbrel			S	Oral	25 Mg, 1x/Day		Unknown
	Enbrel			S	Unknown	25 Mg, Unk		Unknown
	Enbrel			S	Unknown	25 Mg, 1x/Day		Unknown
	Enbrel			S	Subcutaneous	50 Mg, 1x/Day		Unknown
	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Parenteral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	1500 Mg, 2x/Day		Pfizer

Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Unknown	1500 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Oral	Unk, Bid	Pfizer
Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Pfizer
Sulfasalazine	S	Unknown	1000 Mg, Unk	Pfizer
Paracetamol	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
Cimzia	S	Subcutaneous	400 Mg, Monthly	Not Reported
Cimzia	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic Q2wk	Not Reported
Humira	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Rituxan	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Cortisone	S	Oral	Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk Tablet	Not Reported
Cortisone	S	Oral	25 Mg, Unk Tablet	Not Reported
Cortisone	S		25 Mg, Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, 1x/Day (1 Every 24 Hours)	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Other	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Oral	10 Mg, Unk	Not Reported

Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram (5mg/5ml) Unk Syrup	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Folic Acid	S	Oral	25 Mg, Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Mg, Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S		1 Mg, Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported

	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Mg	Not Reported
	Atasol	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Leflunomide	C	Oral	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	11923333	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539178-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection				otherwise specified)	
	Simponi		S	Subcutaneous	Not Reported
	Prednisone		S	Oral	Not Reported
	Plaquenil Sulfate		S	Oral	Not Reported
	Gold		C		Not Reported
	Celebrex		C		Not Reported
	Tofacitinib		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	13113133	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0862		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Prescribed Underdose; Product Use Issue; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	13153195	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Pain;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rocuronium	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Pencillin	S	Unknown	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Rocuronium Bromide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Benzylpenicillin Sodium	S	Unknown		Not Reported
	Phenoxymethylpenicillin	S	Unknown		Not Reported

	Potassium								
	Prednisone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	13380301	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1909275-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Factor Positive; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	13610813	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1627		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Zostavax	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	13875919	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2490		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown	2 Times Per Week	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Imuran	S	Unknown		Not Reported
Plaquenil S	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Oral	2 Times Per Week	Not Reported
Actemra	S	Unknown		Not Reported

	Leflunomide	S	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	13995448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous drip	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	14516337	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2248990-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Pantoloc			S	Unknown	(Enteric Coated)		Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

Palafer Cf	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Naproxen	S	Oral	Not Reported
Naproxen	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Atenolol	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Ascorbic Acid	S	Unknown	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Etanercept	S		Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Pantoprazole	S		Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	Not Reported
Vitamin C	S	Oral	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Naprosyn E	S	Oral	Not Reported

	Palafer	S	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Celebrex	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Celecoxib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	14634899	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0737		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Folic Acid	C	Oral	Not Reported
Folic Acid	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Oral	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Pantoprazol Sodium	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Tenofovir	C	Unknown	Not Reported
Pantoprazol	C	Unknown	Not Reported

	Tenofovir Disoproxil	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Pantoprazole Bluefish	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15258820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2403		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15271033	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2446766-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Gastrointestinal Pain; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac			S				Not Reported
	Diclofenac			S				Not Reported
	Diclofenac			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Voltaren			S	Unknown			Not Reported
	Voltaren			S				Not Reported
	Voltaren			S				Not Reported

	Voltaren		S			Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15305606	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1082		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Advil	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Mefenamic Acid	C	Unknown	Not Reported
	Dequalinium Chloride	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15334491	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019349			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Off Label Use; Rash; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Imuran /00001501/			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk, Qd		Not Reported
	Azathioprine Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15535250	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0858		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Product Complaint; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Abatacept	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
D-Penicillamine	C	Unknown	Not Reported
D-Penicillamine	C	Unknown	Not Reported
Minocycline	C	Unknown	Not Reported
Cyclosporine	C	Unknown	Not Reported
Cyclosporine	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Actemra	C	Unknown	Not Reported
Penicillamine	C	Unknown	Not Reported
Phenylbutazone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15619307	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2554926-00		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blister; Condition Aggravated; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Gait Inability; Joint Swelling; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Oral	Not Reported
	Macrogol 3350	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15728721	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1969198-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown	For 8 Years	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown	For 8 Years	Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Vitamin D3	C	Oral		Not Reported
	Imuran	C			Not Reported
	Gold	C			Not Reported
	Arthrotec	C	Oral		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15732982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1858378-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	15930868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655637-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Infliximab			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	16048867	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059131			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Plaquenil			S		400 Mg, Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Xeljanz			S	Oral	2 Every 1 Day		Not Reported
	Xeljanz			S				Not Reported

	Rituximab	S	Intravenous drip	Solution Intravenous	Not Reported
	Amoxil [Amoxicillin]	C		Unk Unk, Unk	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potassium	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported
	Leflunomide	C			Not Reported
	Bcg	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	16232164	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110764			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary	Hydroxychloroquine			S		Unk		Sanofi
	Sodium Aurothiomalate			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Meloxicam			S		Unk		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Gold			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Solution		Not Reported
	Actemra			S		160 Mg, Qw		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, Qd		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, Qd		Not Reported
	Diclofenac			C		Unk		Not Reported
	Pantoprazole Magnesium			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	16260828	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110686			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Arava			S	Endocervical	20 Mg, Unk		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Actemra			S	Unknown	567 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	16645870	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202595			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Solution Intravenous		Not Reported
	Leflunomide			S	Unknown	Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous			Not Reported
	Desoximetasone			C	Unknown	Not Specified			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	16671604	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077052			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S				Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S				Not Reported
Oxyquinoline Sulfate	S	Unknown			Not Reported
Oxyquinoline Sulfate	S				Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	16865618	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083770		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Treatment Failure; Uveitis	Orencia			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Sarilumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Unk	Not Reported
	Methotrexate	C	Oral		Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17190342	EXPEDITED (15-DAY)		DE, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6054		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Aurothiomalate De Sodium	S	Unknown	Not Reported
	Aurothiomalate De Sodium	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab;Urelumab	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17790373	EXPEDITED (15-DAY)		OT	NVSC2020KR130316		59 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Oral	200-300 Mg, Qd		Novartis
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported

	Prednisolone			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17949468	EXPEDITED (15-DAY)		LT, OT	NVSC2020DE178470		75 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Neuropsychiatric Lupus; Product Use In Unapproved Indication; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17954627	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202006006635			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Neoplasm	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Daily, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17981731	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202006006875			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyarthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17983880	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020251061		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Retinopathy	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Plaquenil S	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17995389	EXPEDITED (15-DAY)		HO	NVSC2020IT190993		78 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Covid-19; Drug Ineffective For Unapproved Indication; Drug Interaction; Dyspnoea; Off Label Use; Product Use In Unapproved Indication; Pyrexia	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S				Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18030409	EXPEDITED (15-DAY)		OT	CA-ACCORD-190393		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown	1 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			C				Not Reported

Ergocalciferol	C	Unknown		Not Reported
Folic Acid	C	Oral	1 Every 1 Days	Not Reported
Humira	C	Subcutaneous		Not Reported
Indapamide	C	Oral	1 Every 1 Days	Not Reported
Naproxen	C	Unknown		Not Reported
Orencia	C	Intravenous (not otherwise specified)		Not Reported
Pantoloc	C	Oral	1 Every 1 Days	Not Reported
Perindopril	C	Oral	1 Every 1 Days	Not Reported
Tylenol	C	Oral		Not Reported
Calcium Carbonate/Calcium Lactogluconate	C	Unknown	Not Specified	Not Reported
Prednisone	S	Unknown	1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18039317	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3482327-00		79 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Transaminases Increased	Kaletra			S	Oral	2 Cp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 12/12h Em D0		Not Reported
	Ogasto			C	Oral			Not Reported
	Bisoprolol			C	Oral			Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)			Not Reported
	Lepicortinolo			C	Oral			Not Reported
	Calcitab D			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Ledertrexato			C	Oral	2,5 Mg 1xdia Po + 2,5 Mg Ao Domingo		Not Reported
	Amlodipine			C	Oral	5 Mg1xdia (21-03 A 23-03)		Not Reported

				E 2,5 Mg (23-03)	
	Olmesartan Medoxomil	C	Oral		Not Reported
	Enoxaparin Sodium	C			Not Reported
	Enoxaparin Sodium	C			Not Reported
	Trazodone	C	Oral		Not Reported
	Irbesartan	C	Oral		Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)		Not Reported
	Lansoprazol	C	Oral		Not Reported
	Prednisolona	C	Oral		Not Reported
	Colecalciferol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18068966	EXPEDITED (15-DAY)		OT	CA-ACCORD-192205		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral	1 Every 1 Days		Accord
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S				Not Reported
	Xeljanz			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported

	Hydroxychloroquine		S	Oral	1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18068974	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-192086		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Hydrochlorothiazide			S	Oral	Frequency: 1 Every 24 Hours		Not Reported
	Methotrexate			S				Accord
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S				Not Reported
	Simponi			C		Solution Subcutaneous		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	1 Every 1 Days		Not Reported
	Hydrochlorothiazide			C	Oral	1 Every 1 Days		Not Reported
	Atenolol/Atenolol Hydrochloride			C	Oral	1 Every 1 Days		Not Reported
	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18070497	EXPEDITED (15-DAY)		HO, OT	CA-DRREDDYS-USA/CAN/20/0125409		11 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Child Abuse; Intentional Product Misuse	Fluoxetine 40mg			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Bisacodyl			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported

Clobazam	S	Oral		Not Reported
Clonidine	S	Oral	0.05mg Every Morning And 0.1mg Every Evening	Not Reported
Colecalciferol	S	Oral	2000 Units Daily	Not Reported
Dimenhydrinate	S			Not Reported
Diphenhydramine	S	Oral		Not Reported
Fluticasone Propionate	S	Unknown	250 Mcg/Actuation	Not Reported
Gabapentin	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydromorphone	S			Not Reported
Ketorolac	S	Oral		Not Reported
Leuprorelin	S	Intramuscular		Not Reported
Lorazepam	S	Sublingual	0.5mg And 2mg As Required	Not Reported
Melatonin	S	Oral		Not Reported
Methadone	S	Oral		Not Reported
Montelukast	S	Oral		Not Reported
Pantoprazole	S	Oral		Not Reported
Phenobarbital	S	Oral		Not Reported
Polyethylene Glycol	S	Oral		Not Reported
Ranitidine	S	Oral		Not Reported
Salbutamol Sulfate	S		2 Puffs Daily (100 Microg Per Actuation)	Not Reported
Vitamin D3	S	Oral		Not Reported
Leuprolide	S	Intramuscular		Not Reported
Ascorbic Acid	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18094882	EXPEDITED (15-DAY)		OT	CA-ACCORD-193347			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Methotrexate	S	Oral	Accord
	Xeljanz	S		Not Reported
	Tocilizumab	S		Not Reported
	Sulfasalazine	S		Not Reported
	Simponi	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Leflunomide	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Cimzia	C		Not Reported
	Prednisone	C		Not Reported
	Methotrexate	S	Subcutaneous	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095088	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807007		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095109	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807003		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Lung Disorder; Off Label Use; Toxicity To Various Agents	Methotrexate		S	Unknown		Barr
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		C	Oral		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Acetaminophen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095116	EXPEDITED (15-DAY)		DE, HO, OT	GB-ADVANZ PHARMA-202007007411			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Disease Progression; Mechanical Ventilation; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095173	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095174	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity; Treatment Failure	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095177	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095585	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806941			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Pulmonary Toxicity	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095596	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095632	EXPEDITED (15-DAY)		OT	CA-ACCORD-193517		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Methotrexate			S	Oral			Not Reported
	Enbrel			S		Frequency: 1 Every 1 Weeks		Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Benadryl			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Benadryl			C				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095694	NON-EXPEDITED			US-ADVANZ PHARMA-202007007407			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Patient Dissatisfaction With Treatment	Hydroxychloroquine			S	Oral	200mg Tablet By Mouth One And A Half Everyday		Concordia
	Methotrexate			S	Oral	8 Dosage Form, Weekly		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095770	EXPEDITED (15-DAY)		OT	CA-ACCORD-192677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18095772	EXPEDITED (15-DAY)		OT	CA-ACCORD-192499		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness	Methotrexate			S	Unknown	1 Every 1 Weeks, Not Specified 1 Every 1 Days		Accord
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	2 Every 1 Days, 2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Xeljanz	S			Not Reported
Paracetamol	C	Unknown	Not Specified	Not Reported
Anakinra	C	Unknown		Not Reported
Ativan	C	Unknown	Not Specified	Not Reported
Codeine	C	Unknown		Not Reported
Darifenacin	C	Unknown		Not Reported
Dexamethasone	C	Intramuscular	Not Specified	Not Reported
Dilaudid	C	Unknown	Not Specified	Not Reported
Diphenhydramine	C	Unknown		Not Reported
Furosemide	C	Unknown	Not Specified, 3 Every 1 Days	Not Reported
Hydromorphone/Hydromorphone Hydrochloride	C	Unknown	Not Specified	Not Reported
Kadian	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Metered Dose	Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoprazole	C	Unknown	Not Specified	Not Reported
Restasis	C	Unknown	Emulsion	Not Reported
Synthroid	C	Unknown	Not Specified	Not Reported
Triamcinolone	C	Intra-articular		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown		Not Reported
Vagifem	C	Vaginal		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous; 2 Every 1 Days	Not Reported
Hydroxychloroquine	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096168	EXPEDITED (15-DAY)		OT	CA-ACCORD-193422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096298	EXPEDITED (15-DAY)		LT, OT	CA-APOTEX-2020AP014479		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Iron Decreased; Blood Pressure Increased; Headache; Interstitial Lung Disease; Joint Swelling; Monocyte Count Increased; Muscle Spasms; Osteoporosis; Oxygen Saturation Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Walking Aid User	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolic Acid			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Minocycline			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Accupril			C	Unknown	Unk		Not Reported
	Apo-Atorvastatin			C	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			C	Unknown	Unk		Not Reported
	Apo-Prednisone			C	Unknown	Unk		Not Reported
	Apo-Zopiclone			C	Unknown	Unk		Not Reported

	Gabapentin	C	Unknown	Unk	Not Reported
	Lactaid	C	Unknown	Unk	Not Reported
	Lactulose	C	Unknown	Unk	Not Reported
	Levemir	C	Unknown	Unk	Not Reported
	Nabilone	C	Unknown	Unk	Not Reported
	Novorapid	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Pms-Cetirizine	C	Unknown	Unk	Not Reported
	Methadone	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096412	EXPEDITED (15-DAY)		OT	AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2020-04022			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1	Rosuvastatin			S	Unknown	Unk		Alkem
	Aspirin			S	Unknown	Unk		Not Reported
	Cholecalciferol			S	Unknown	Unk		Not Reported
	Ezetimibe			S	Unknown	Unk		Alkem
	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Paracetamol			S	Unknown	Unk		Not Reported
	Prasugrel Hydrochloride			S	Unknown	Unk		Alkem
	Sildenafil			S	Unknown	Unk		Alkem
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Ivabradine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Methotrexate	S	Unknown	Unk		Not Reported
	Prednisolone	S	Unknown	Unk		Not Reported
	Ramipril	S	Unknown	Unk		Not Reported
	Reboxetine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Topiramate	S	Unknown	Unk		Not Reported
	Endone	S	Unknown	Unk		Not Reported
	Glucagen	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Mirena	S	Unknown	Unk		Not Reported
	Novorapid	S	Unknown	Unk		Not Reported
	Oxycontin	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096508	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-193340		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During	Alendronate Sodium/Alendronic Acid			S	Oral			Accord
	Methotrexate			S	Oral	Frequency: 1 Every 1 Days		Accord
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine/Pseudoephedrine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Folic Acid	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil	S	Oral	Frequency: 1 Every 1 Days	Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Topicort	S	Cutaneous		Not Reported
	Tofacitinib	S		Frequency: 2 Every 1 Days	Not Reported
	Salazopyrin	C			Not Reported
	Atasol [Paracetamol]	C			Not Reported
	Methotrexate	S	Oral		Accord
	Folic Acid	S			Not Reported
	Hydroxychloroquine	S	Oral	Frequency: 1 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Sulfasalazine	S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Tofacitinib	S		Frequency: 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806840			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096564	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096566	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806830		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Rheumatoid Arthritis; Stress Fracture; Vomiting	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096569	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806486		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096621	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806980		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096769	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Magnesium Sulfate			S	Unknown			Not Reported
	Cyanocobalamin			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Buprenorphine			S	Unknown			Not Reported
	Fish Oil			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Pyridoxine Hydrochloride	S	Unknown		Not Reported
	Rivaroxaban	S	Unknown		Not Reported
	Vitamin B6	S	Unknown		Not Reported
	Vitamin D [Colecalciferol]	S	Unknown		Not Reported
	Magnesium Gluconate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096790	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806512		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18096844	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807010		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Rotator Cuff Syndrome; Swelling; Tongue Ulceration; Tooth Infection	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Indometacin		C		Not Reported
	Prednisone		C		Not Reported
	Tramadol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097014	EXPEDITED (15-DAY)		HO, LT, OT	BR-LUPIN PHARMACEUTICALS INC.-2020-03816		67 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; White Blood Cell Count Increased	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Lupin
	Ceftriaxone			S	Unknown	2 Gram, Qd		Lupin
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk, 400 Mg + 80 Mg, 1.5 Ampule, 8/8 Hs) For Ten Days		Novel Labs
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Meronem			S	Unknown	1000 Milligram (8/8 Hs)		Not Reported
	Clexane			C	Unknown	20 Milligram, Qd		Not Reported
	Clexane			C	Unknown	60 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097024	EXPEDITED (15-DAY)		OT	CA-ACCORD-193115		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Loss Of Employment;	Hydrochlorothiazide			S				Not Reported
	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord
	Apo-Hydroxyquine			S				Not Reported
	Cefalexin			S				Not Reported
	Enalapril			S				Not Reported

Product Use Issue	Enbrel	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Not Reported
	Isoniazid	S			Not Reported
	Losartan	S			Not Reported
	Metoprolol	S			Not Reported
	Orencia	S			Not Reported
	Benzylpenicillin	S			Not Reported
	Xeljanz	S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Atenolol/Atenolol Hydrochloride	C			Not Reported
	Colchicine	C			Not Reported
	Coversyl	C			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	C			Not Reported
	Folinic Acid	C			Not Reported
	Levothyroxine	C			Not Reported
	Ranitidine	C			Not Reported
	Methotrexate	S			Accord
	Benzylpenicillin	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097026	EXPEDITED (15-DAY)		OT	CA-ACCORD-193117		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Loss Of Employment; Product Use Issue	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Hydrochlorothiazide			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cefalexin			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Isoniazid			S	Unknown			Not Reported
	Losartan			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Benzylpenicillin	S	Unknown		Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Ranitidine	C			Not Reported
	Atenolol/Atenolol Hydrochloride	C			Not Reported
	Colchicine	C			Not Reported
	Coversyl	C			Not Reported
	Esomeprazole	C			Not Reported
	Folinic Acid	C			Not Reported
	Levothyroxine	C			Not Reported
	Methotrexate	S	Unknown		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097204	EXPEDITED (15-DAY)		LT, OT	CH-LUPIN PHARMACEUTICALS INC.-2020-03826		76 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Inflammatory Marker Increased; Rash	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Clobetasol Propionate			S	Unknown	0.05 Percent Unk (Ointment)		Novel Labs
	Mometasone Furoate			S		0.1 Percent		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097244	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-216942		13 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methylprednisolone			S	Oral	48 Milligram, Daily		Not Reported
	Methylprednisolone			S	Oral	8 Milligram, Daily		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk Unk, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097364	EXPEDITED (15-DAY)		DE	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-024240		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Toxicity To Various Agents	Zopiclone			S	Oral	Unspecified ()		Not Reported
	Gabapentine			S	Oral			Zydus Pharm
	Mirtazapine			S	Oral	Unspecified ()		Zydus Pharm
	Ethanol			S	Oral	Unspecified ()		Not Reported
	Hydroxychloroquine			S	Oral	Unspecified		Not Reported
	Morphine			S	Oral	Unspecified ()		Not Reported
	Amitriptyline			S	Oral			Not Reported
	Oxazepam			S	Oral	Unspecified ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097418	EXPEDITED (15-DAY)		OT	NVSC2020IT213583		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema Multiforme; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Lopinavir,Ritonavir			S	Unknown	200/50 Mg (2 Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097474	EXPEDITED (15-DAY)		OT	CA-ACCORD-192684			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia;	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported

Nephrolithiasis; Product Dose Omission; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097476	EXPEDITED (15-DAY)		OT	CA-ACCORD-193120		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Pain; Peripheral Swelling; Rash; Swelling; Tenosynovitis; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Accord
	Benzylpenicillin			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097492	EXPEDITED (15-DAY)		OT	CA-ACCORD-193256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Prednisone			S	Oral	1 Every 24 Hours		Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	1 Every 24 Hours		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097495	EXPEDITED (15-DAY)		OT	CA-ACCORD-193201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806837		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug	Methotrexate			S	Unknown			Barr

Ineffective; Neck Pain; Neck Surgery; Spinal Column Injury; Surgical Failure	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Mobicox	C	Unknown	15 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097525	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806405		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097534	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1806842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097539	EXPEDITED (15-DAY)		OT	CA-ACCORD-193425		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Methotrexate			S	Unknown			Accord
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097542	EXPEDITED (15-DAY)		OT	CA-ACCORD-193483		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Every 1 Days	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097545	EXPEDITED (15-DAY)		OT	CA-ACCORD-193589		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Dorzolamide			C	Unknown	2 Every 1 Days		Not Reported

Hydrochloride/Timolol Maleate					
Ergocalciferol	C	Unknown	Not Specified 1 Every 1 Weeks		Not Reported
Estradiol	C	Unknown	3 Every 1 Days		Not Reported
Furosemide	C	Unknown	Not Specified 1 Every 1 Days		Not Reported
Potassium	C	Unknown	Not Specified 1 Every 1 Days		Not Reported
Morphine	C	Unknown	Not Specified		Not Reported
Valsartan	C	Unknown	Not Specified 1 Every 1 Days		Not Reported
Xalatan	C	Unknown	Dosage Form: Solution Ophthalmic 1 Every 1 Days		Not Reported
Zingiber Officinale/Zingiber Officinale Rhizome	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097549	EXPEDITED (15-DAY)		OT	CA-ACCORD-193427			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S				Accord
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097551	EXPEDITED (15-DAY)		OT	CA-ACCORD-193428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Contraindicated Product Administered; Joint Swelling; Product Use Issue; Treatment Failure	Methotrexate		S	Subcutaneous		Accord
	Enbrel		S			Not Reported
	Arava		S			Not Reported
	Hydroxychloroquine		S			Not Reported
	Orencia		S			Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097552	EXPEDITED (15-DAY)		OT	CA-ACCORD-193268		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rabeprazole			C	Unknown			Not Reported
	Tramadol			C	Oral	Not Specified		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097592	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807001		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097757	EXPEDITED (15-DAY)		DE, OT	CH-TEVA-2020-CH-1795772		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Hepatic Enzyme Increased	Co-Amoxi Mepha			S	Intravenous drip	In Total		Teva
	Paracetamol			S	Unknown	500 Mg At 4g/Day From 25 Mar To 17 Apr Oral Or Intravenous		Not Reported
	Reyataz			S	Oral	400 Mg/Day From 25 To 31 Mar, Except 30 Mar: 800 Mg/Day		Not Reported
	Plaquenil			S	Oral	400 Mg: 2 Doses 12 Hours Apart Around 25 Mar, Then 200 Mg/D From 26 Mar To 28 Mar		Not Reported
	Tazobac			S	Intravenous drip			Not Reported
	Midazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Rocuronium			C		30mg From 27 Mar To 06 Apr Then From 11 To 14 Apr		Not Reported
	Propofol			C				Not Reported
	Ketamine			C		From 01 Apr To 05 Apr Then From 10 Apr To 17 Apr		Not Reported
	Cefepime			C				Not Reported
	Meropenem			C				Not Reported
	Enoxaparin			C				Not Reported
	Sotalol			C		80 Mg, Suspended On Admission, Resumed From 08 Apr To 17 Apr		Not Reported
	Metoprolol			C		25-50 Mg On 28 Mar, 29		Not Reported

				Mar, 5-6 Apr	
	Hydrochlorothiazide	C			Not Reported
	Furosemide	C			Not Reported
	Aspirin	C		100 Mg	Not Reported
	Esomeprazole	C		40 Mg/Day	Not Reported
	N-Acetylcysteine	C			Not Reported
	Acenocoumarol	C		2 Mg	Not Reported
	Atorvastatin	C		10 Mg	Not Reported
	Tamsulosin	C		0.3 Mg	Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097819	EXPEDITED (15-DAY)		OT	CA-ACCORD-192819		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response	Methotrexate			S	Unknown			Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Paracetamol			C				Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C				Not Reported

Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Oxycontin	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097837	EXPEDITED (15-DAY)		OT	CA-ACCORD-192870		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Off Label Use; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate			S	Unknown			Accord
	Rosuvastatin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097871	EXPEDITED (15-DAY)		OT	CA-ACCORD-193126		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097874	EXPEDITED (15-DAY)		OT	CA-ACCORD-193538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown	Not Specified		Not Reported
	Sulfasalazine			C	Oral	1 Every 1 Days		Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097884	EXPEDITED (15-DAY)		OT	CA-ACCORD-193336		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder; Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis; Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Accord
	Azithromycin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097957	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807019		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

Rheumatoid Factor Positive; Synovitis; Vomiting	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099037	EXPEDITED (15-DAY)		DE, OT	CH-PFIZER INC-2020246550		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Hepatic Enzyme Increased	Tazobac			S	Intravenous drip	4.5 G, 3x/Day		Pfizer
	Piperacillin/Tazobactam			S		4.5 G		Pfizer
	Reyataz			S	Oral	400 Mg, Daily		Not Reported
	Reyataz			S	Oral	800 Mg, Daily		Not Reported
	Reyataz			S	Oral	400 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Daily		Not Reported
	Rocuronium [Rocuronium Bromide]			S		30 G		Not Reported
	Rocuronium [Rocuronium Bromide]			S		30 G		Not Reported
	Co-Amoxi			S	Intravenous drip	2.2 G In Total		Not Reported
	Paracetamol			S		4 G, Daily		Not Reported
	Midazolam			S		Unk		Not Reported
	Fentanyl			S		Unk		Not Reported
	Propofol			S		30 Mg		Not Reported
	Enoxaparin			S		Unk		Not Reported
	Sotalol			S		Unk		Not Reported
	Sotalol			S		Unk		Not Reported
	Metoprolol			S		25-50 Mg		Not Reported
	Metoprolol			S		25-50 Mg		Not Reported

Metoprolol	S	25-50 Mg	Not Reported
Aspirin [Acetylsalicylic Acid]	S	100 Mg	Not Reported
Ketamine Hcl	C	Unk	Not Reported
Ketamine Hcl	C	Unk	Not Reported
Meropenem	C	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Hydrochlorothiazide	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Esomeprazole	C	40 Mg, Daily	Not Reported
N-Acetylcysteine	C	Unk	Not Reported
Acenocoumarol	C	2 Mg	Not Reported
Sotalol	C	80 Mg	Not Reported
Atorvastatin	C	10 Mg	Not Reported
Tamsulosin	C	0.3 Mg	Not Reported
Vitamin D3	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099118	EXPEDITED (15-DAY)		OT	CA-ACCORD-192828		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S		1 Every 1 Weeks		Accord
	Actemra			S				Not Reported
	Arava			S		1 Every 1 Days		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Subcutaneous	2 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S				Not Reported

	Dilaudid	C	Not Reported
	Furosemide	C	Not Reported
	Hydromorphone/Hydromorphone Hydrochloride	C	Not Reported
	Kadian	C	Not Reported
	Kenalog	C	Not Reported
	Lasix	C	Not Reported
	Morphine	C	Not Reported
	Norflex	C	Not Reported
	Omnaris	C	Not Reported
	Pantoloc	C	Not Reported
	Pantoprazole	C	Not Reported
	Restasis	C	Not Reported
	Synthroid	C	Not Reported
	Trimethoprim	C	Not Reported
	Urispas	C	Not Reported
	Vagifem	C	Not Reported
	Paracetamol	C	Not Reported
	Anakinra	C	Not Reported
	Ativan	C	Not Reported
	Benadryl	C	Not Reported
	Codeine	C	Not Reported
	Darifenacin	C	Not Reported
	Desoximetasone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099131	EXPEDITED (15-DAY)		OT	CA-ACCORD-193536			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Furuncle; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C				Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099182	EXPEDITED (15-DAY)		OT	IT-PBT-000068			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Gastrointestinal Disorder; Hypertransaminasaemia; Product Use In Unapproved Indication; Product Use In Unapproved Indication	Tacrolimus			S	Unknown			Panacea Biotec
	Mycophenolate Mofetil			S	Unknown			Panacea Biotec
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Cyclophosphamide			S	Oral			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Fluconazole			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099254	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1068654		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bk Virus Infection; Corynebacterium Infection; Covid-19; Enterococcal Infection; Malnutrition; Morganella Infection; Off Label Use; Pleural Effusion; Pneumonia; Pneumonia Klebsiella; Pulmonary Oedema; Renal Tubular	Mycophenolate Mofetil			S	Unknown	2000 Milligram, Qd		Mylan
	Mycophenolate Mofetil			S	Unknown	1000 Milligram, Qd		Mylan
	Mycophenolate Mofetil			S	Unknown	500 Milligram, Qd		Mylan
	Prednisone			S	Unknown	100 Milligram		Mylan
	Prednisone			S	Unknown	5 Milligram, Qd		Mylan
	Tacrolimus			S	Unknown	Unknown Initial Dose		Mylan
	Tacrolimus			S	Unknown	Dose Corresponding To A		Mylan

Necrosis; Respiratory Failure; Staphylococcal Bacteraemia; Staphylococcal Infection; Stenotrophomonas Infection; Urinoma					Trough Goal Of 5-8 Microg/Ml.	
	Azithromycin		S	Unknown	250 Milligram, Qd	Mylan
	Hydroxychloroquine		S	Unknown	200 Milligram, Bid	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099263	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007419			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099311	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-23710		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Advil [Ibuprofen]			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported
	Ketorolac			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported
	Naproxen			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

	Xeljanz		C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099595	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Bacitracin			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Neomycin Sulfate			S	Unknown	Unknown		Not Reported
	Polymyxin B Sulfate			S	Unknown	Unknown		Not Reported
	Prednisone			C	Intramuscular	Unknown		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099667	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3482385-00		49 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Nausea; Transaminases Increased; Vomiting	Kaletra			S	Oral	2 Cp 12/12h		Not Reported
	Plaquinol			S	Oral	400mg 12/12h Em D0		Not Reported
	Potassium Chloride			C	Intravenous (not otherwise specified)			Not Reported
	Montelukast			C	Oral			Not Reported
	Furosemide			C				Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported

	Trazodone	C	Oral		Not Reported
	Trazodone	C	Oral		Not Reported
	Metamizole Magnesium	C	Oral		Not Reported
	Paracetamol	C	Oral		Not Reported
	Sodium Chloride	C	Intravenous (not otherwise specified)		Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)		Not Reported
	Metoclopramide	C		10 Mg Sos (23-03 A 25-03); 10 Mg 3xdia (25-03 A 27-03)10 Mg Sos (27-03 A 04-02)	Not Reported
	Monopotassium Phosphate	C	Intravenous (not otherwise specified)		Not Reported
	Escitalopram	C	Oral	10 Mg 1xdia (Ate 25-03) E 20 Mg (02-04)	Not Reported
	Zofran [Ondansetron]	C	Oral		Not Reported
	Ondansetron	C			Not Reported
	Oxazepam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099681	EXPEDITED (15-DAY)		OT	CA-009507513-2007CAN011650			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Januvia			S	Unknown	Dosage Form: Not Specified		Merck
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Dosage Form: Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18100355	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-021543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown			Santarus
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18100470	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP014454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Bisoprolol			S	Unknown	12.5 Milligram, Qd		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	12.5 Milligram, Qd		Apotex
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Buprenorphine			S	Unknown	10 Milligram, Qd		Not Reported
	Cyanocobalamin			S	Unknown	Unk		Not Reported

	Fish Oil	S	Unknown	Unk	Not Reported
	Furosemide;Potassium Chloride	S	Unknown	Unk	Not Reported
	Lasix [Furosemide]	S	Unknown	20 Milligram	Not Reported
	Magnesium Gluconate	S	Unknown	Unk	Not Reported
	Pyridoxine Hydrochloride	S	Unknown	Unk	Not Reported
	Rivaroxaban	S	Unknown	15 Milligram, Qd	Not Reported
	Vitamin B6	S	Unknown	Unk	Not Reported
	Vitamin D [Colecalciferol]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18100913	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487393		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Hydroxychloroquine			S	Oral	400 Mg, Bid		Not Reported
	Albumin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Potassium Chloride			C				Not Reported
	Propofol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Furosemide			C				Not Reported
	Insulin			C				Not Reported
	Ivermectin			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	17916287	EXPEDITED (15-DAY)		HO	CA-ACCORD-185738		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Alendronate Sodium/Alendronic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Unknown	1 Every 1 Months		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S		1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 1 Weeks, Solution Subcutaneous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Myochrysine			S	Parenteral	1 Every 1 Months, Solution Intramuscular		Not Reported
	Orencia			S	Unknown	1 Every 1 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Leflunomide			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Every 12 Hours		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			C		1 Every 1 Days		Not Reported
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S		2 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord

	Methotrexate		S	Unknown	1 Every 1 Weeks	Accord
	Tocilizumab		S	Unknown	1 Every 4 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	17983547	EXPEDITED (15-DAY)		OT	CA-ACCORD-188745		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	1 Every 1 Months, Solution Subcutaneous		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	17994488	EXPEDITED (15-DAY)		HO	CA-ACCORD-188717		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate	S		1 Every 2 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Every 2 Weeks	Not Reported
	Anakinra	S	Subcutaneous	1 Every 1 Days	Not Reported
	Enbrel	S	Unknown	1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Immunoglobulin (Immunoglobulin G Human)	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Naproxen	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Prednisone	S	Oral	2 Every 1 Days	Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days	Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone	C	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	12 Every 2 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	1 Every 1 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Minutes	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18048857	EXPEDITED (15-DAY)		OT	CA-ACCORD-191206		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective;	Methotrexate			S				Not Reported
	Actemra			S				Not Reported

Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Arava		S	Oral		Not Reported
	Cetirizine		S			Not Reported
	Cimzia		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Desoximetasone		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S			Not Reported
	Fosamax		S			Not Reported
	Humira		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Phthalylsulfathiazole		S			Not Reported
	Prednisone		S			Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Desoximetasone		S	Cutaneous		Not Reported
	Hydroxychloroquine		S			Not Reported
	Hydroxychloroquine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18068548	EXPEDITED (15-DAY)		OT	CA-ACCORD-192208			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling;	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported

Systemic Lupus Erythematosus	Cortisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	Not Specified	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown	Not Specified	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Specified	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18069105	EXPEDITED (15-DAY)		OT	CA-ACCORD-192190		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S				Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18073415	EXPEDITED (15-DAY)		OT	CA-ACCORD-191885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Oral			Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine/Pseudoephedrine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S				Not Reported
	Desoximetasone			S				Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil			S		Frequency: 1 Every 1 Days		Not Reported
	Pseudoephedrine			S				Not Reported
	Reactine (Cetirizine)			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Sarilumab	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Stelara	S				Not Reported
Sulfasalazine	S	Oral	Frequency: 2 Every 1 Days		Not Reported
Hydrocortisone	S	Subcutaneous			Not Reported
Xeljanz	S		Frequency: 2 Every 1 Days		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Folic Acid	S				Not Reported
Plaquenil	S				Not Reported
Folic Acid	S	Unknown			Not Reported
Hydrocortisone	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18100356	EXPEDITED (15-DAY)		HO, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254816		44 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Off Label Use; Premature Delivery	Azithromycin			S	Unknown	Unk		Sun
	Fentanyl			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Midazolam			S	Unknown	Unk		Sun
	Noradrenaline			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18100968	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2020-037145		56 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquinol			S	Oral	400 Milligram, Once A Day (400mg 12/12h Em D0 E Depois 200mg 12/12h)		Not Reported
	Flucloxacillin			C	Intravenous (not otherwise specified)	12000 Milligram, Once A Day		Not Reported
	Metamizole Magnesium			C	Intravenous (not otherwise specified)	2000 Milligram, As Necessary		Not Reported
	Metamizole Magnesium			C	Oral	575 Milligram, As Necessary		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2000 Milligram, Once A Day		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	1000 Milliliter, Once A Day		Not Reported
	Gentamicin			C	Intravenous (not otherwise specified)	240 Milligram, Once A Day		Not Reported
	Paracetamol			C	Oral	1000 Milligram, As Necessary		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	1000 Milligram, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101039	EXPEDITED (15-DAY)		OT	CA-ACCORD-193423		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Unknown	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Prednisone	C		Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101042	EXPEDITED (15-DAY)		OT	CA-ACCORD-193414		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S		Frequency: 1 Every 1 Weeks		Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Oral	Frequency: 1 Every 24 Hours		Not Reported
	Enbrel			S		Frequency: 2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Frequency: 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S		Frequency: 2 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous, Frequency: 1 Every 6 Weeks		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Leflunomide			S	Oral	Frequency: 1 Every 1 Days		Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported
	Bupropion/Bupropion Hydrochloride			C	Oral			Not Reported
	Methotrexate			S		Frequency: 1 Every 1 Weeks		Not Reported

	Hydroxychloroquine	S		Frequency: 2 Every 1 Days	Not Reported
	Methotrexate	S		Frequency: 1 Every 1 Weeks	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101047	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-193424			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101132	EXPEDITED (15-DAY)		OT	CA-ACCORD-193633			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate	S	Unknown		Accord
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Certolizumab	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Aurothioglucose	S	Other		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101133	EXPEDITED (15-DAY)		OT	CA-ACCORD-193630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C				Not Reported

	Premarin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101139	EXPEDITED (15-DAY)		OT	CA-ACCORD-193679		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C		Not Specified		Not Reported
	Hydrodiuril			C				Not Reported
	Neurontin			C	Unknown	Not Specified		Not Reported
	Premarin			C		Not Specified		Not Reported
	Tylenol			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101245	EXPEDITED (15-DAY)		OT	CA-ACCORD-193617		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

			otherwise specified)	Intravenous	
	Risedronic Acid	S			Not Reported
	Rituximab	S			Not Reported
	Hydroxychloroquine	C			Not Reported
	Methotrexate	S	Subcutaneous		Accord
	Hydroxychloroquine	S	Oral		Not Reported
	Risedronic Acid	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101249	EXPEDITED (15-DAY)		OT	CA-ACCORD-193591		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Arthrotec			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101263	EXPEDITED (15-DAY)		OT	CA-ACCORD-193675			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101264	EXPEDITED (15-DAY)		OT	CA-ACCORD-193684		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported
	Apo-Acetaminophen			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Dilaudid			S				Not Reported
	Enbrel			S				Not Reported
	Hydromorphone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101265	EXPEDITED (15-DAY)		OT	CA-ACCORD-193686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	Not Specified, 1 Every 24 Hours		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Meloxicam			C	Unknown	Not Specified		Not Reported
	Sulfasalazine			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101267	EXPEDITED (15-DAY)		OT	CA-ACCORD-193687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101268	EXPEDITED (15-DAY)		OT	CA-ACCORD-193694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Accord
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101285	EXPEDITED (15-DAY)		OT	CA-ACCORD-192679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101288	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-193699		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Accord
	Actemra			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Meloxicam			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101289	EXPEDITED (15-DAY)		HO	CA-ACCORD-193698		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Oral		Not Reported
	Minocycline	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ilaris	C		Powder For Solution Subcutaneous	Not Reported
	Lyrica	C	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101313	EXPEDITED (15-DAY)		OT	CA-ACCORD-193558		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Therapeutic Product Effect Decreased; Ulcer	Methotrexate			S	Unknown			Accord
	Etanercept			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown	1 Every 1 Days		Not Reported
	Xeljanz			S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Celebrex			S	Oral	2 Every 1 Days		Not Reported
	Betaloc			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Losec			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101324	EXPEDITED (15-DAY)		OT	CA-ACCORD-193641		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Hypersensitivity; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	1 Every 1 Day		Not Reported
	Enbrel			S	Unknown	2 Every 1 Weeks		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 1 Month		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown	1 Every 6 Hours		Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Dyclonine			C	Unknown			Not Reported
	Furosemide			C	Unknown	1 Every 8 Hours		Not Reported
	Kadian			C	Unknown			Not Reported
	Kenalog			C	Unknown			Not Reported
	Loperamide			C	Unknown	1 Every 12 Hours		Not Reported
	Morphine			C	Unknown			Not Reported

Omnaris	C	Unknown	Metered Dose		Not Reported
Hydromorphone/Hydromorphone Hydrochloride	C	Unknown			Not Reported
Orphenadrine	C	Unknown	1 Every 12 Hour		Not Reported
Oxyneo	C	Unknown			Not Reported
Pantoprazole	C	Unknown			Not Reported
Restasis	C	Unknown	Emulsion		Not Reported
Synthroid	C	Unknown			Not Reported
Trimethoprim	C	Unknown			Not Reported
Urispas	C	Unknown			Not Reported
Vagifem	C	Vaginal			Not Reported
Hydroxychloroquine	S	Unknown	1 Every 12 Hours		Not Reported
Hydroxychloroquine	S	Unknown	1 Every 12 Hours		Not Reported
Methotrexate	S	Unknown	1 Every 1 Weeks		Accord
Orencia	S	Unknown			Not Reported
Pantoprazole	C	Unknown			Not Reported
Sodium Aurothiomalate	S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101338	EXPEDITED (15-DAY)		OT	CA-ACCORD-193752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xejanz			C	Oral			Not Reported

	Hydroxychloroquine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101339	EXPEDITED (15-DAY)		OT	CA-ACCORD-193688		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101340	EXPEDITED (15-DAY)		OT	CA-ACCORD-193689			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Oral	1 Every 1 Weeks, Not Specified		Accord
	Tocilizumab			S	Intravenous (not otherwise specified)	1 Every 1 Months, Not Specified		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Weeks		Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101345	EXPEDITED (15-DAY)		OT	CA-ACCORD-193724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Accord
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole			C	Oral	1 Every 1 Days		Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101347	EXPEDITED (15-DAY)		OT	CA-ACCORD-193735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug	Methotrexate			S	Oral	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mitral Valve Disease; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Bactrim		S	Oral	Not Specified	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101348	EXPEDITED (15-DAY)		OT	CA-ACCORD-193640		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations	Methotrexate			S	Oral			Accord
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Ergocalciferol			C				Not Reported
	Folinic Acid			C				Not Reported
	Coversyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101355	EXPEDITED (15-DAY)		OT	CA-ACCORD-193712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain;	Methotrexate			S	Oral	1 Every 1 Days		Accord

Rheumatoid Arthritis; Treatment Failure	Actemra	S	Unknown	Not Specified	Not Reported
	Arava	S	Oral	1 Every 1 Days	Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	C	Oral	Not Specified	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Folic Acid	C	Oral	Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101361	EXPEDITED (15-DAY)		HO	CA-ACCORD-193260			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Methotrexate			S	Oral	1 Every 1 Weeks, Not Specified		Accord
	Actemra			S	Subcutaneous	Not Specified, 1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 24 Hours		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cymbalta			C		Not Specified		Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101402	EXPEDITED (15-DAY)		OT	CA-ACCORD-193659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium/Rocuronium Bromide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809460		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C		7.5 Milligram Daily;		Not Reported
	Leflunomide			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101439	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807792		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Naproxen			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101444	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807749		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Apo-Leflunomide		S	Oral		Not Reported
	Apo-Leflunomide		S	Oral	20 Milligram Daily;	Not Reported
	Arava		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101468	EXPEDITED (15-DAY)		HO, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254826		29 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown			Ipca
	Methyldopa			S	Unknown	1 Gram, Daily		Sun
	Betamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101474	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255176		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Death; Drug Ineffective; Heparin-Induced Thrombocytopenia; Hypotension; Platelet Count Decreased; Pulmonary Embolism; Tachycardia	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Bivalirudin			S	Unknown	0.15 Mg/Kg/H		Not Reported
	Unfractionated Heparin			S	Unknown	5000 Unit, Bid		Not Reported
	Unfractionated Heparin			S		18 Units/Kg/H		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Cisatracurium			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported

	Norepinephrine	S	Unknown	Unk		Not Reported
	Nitric Oxide	S		Unk		Not Reported
	Tenecteplase	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101475	EXPEDITED (15-DAY)		HO, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-254829			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental			Sun
	Hydroxychloroquine			S	Transplacental			Ipca
	Methyldopa			S	Unknown			Sun
	Betamethasone			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18101706	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-03984		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Darunavir			S	Unknown	800 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Ritonavir			C	Unknown	100 Milligram, Qd		Not Reported
	Enoxaparin			C	Unknown	6000 International Unit, Bid		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Clarithromycin			C	Unknown	500 Milligram		Not Reported
	Clarithromycin			C				Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18101748	EXPEDITED (15-DAY)		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-03936		1 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk (Day 3 To Day 11)		Lupin
	Teicoplanin			C	Unknown	Unk, (Day 6 To Day 14)		Not Reported
	Lopinavir/Ritonavir			C	Unknown	Unk, (Day 4 To Day 12)		Not Reported
	Fluconazole			C	Unknown	Started On Day 3		Not Reported
	Piperacillin/Tazobactam			C	Unknown	Unk, Day 3 To Day 18		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18101751	EXPEDITED (15-DAY)		HO, OT	NL-LUPIN PHARMACEUTICALS INC.-2020-03910		57 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Etanercept			S	Subcutaneous	1 Dosage Form, Weekly (Solution For Injection)		Lupin
	Etanercept			S	Subcutaneous	Unk (Solution For Injection)		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Unknown	Unk		Lupin
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Dosage Form, Qd		Not Reported
	Sulfasalazine			S	Oral	2 Dosage Form (2 Df,Unk; Tablets))		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	1 Dosage Form Weekly		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported

	Pantoprazole		C	Unknown	Unk	Not Reported
	Hydrochlorothiazide With Triamterene		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	12890986	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013207		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Apo-Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Fentanyl			S	Unknown	Unk		Apotex
	Celecoxib			S	Oral	Unk		Apotex
	Celecoxib			S				Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Nortriptyline			S	Oral	10 Mg, Unk		Not Reported
	Sulfasalazin			S	Oral	2.5 G, Qd		Not Reported
	Sulfasalazin			S	Oral	500 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk (Occlusive Dressing Technique)		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q.3w		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported

Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q.3w	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T., 1 Every 1 Month	Not Reported
Arava	S	Oral	20 Mg, Qd, 1 Every 1 Day	Not Reported
Arava	S	Oral	20 Mg, Q.M.T.	Not Reported
Orencia	S	Vaginal	750 Mg, Q.M.T.	Not Reported
Vitamin B1 /00056101/	S	Unknown	Unk	Not Reported
Vitamin B1 /00056101/	S	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Prn	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk, 1.0 Dosage, As Required	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	Unk	Not Reported
Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported

Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Q.Wk.	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Intravenous (not otherwise specified)	400 Iu, Q.Wk.	Not Reported
Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium	C	Unknown	400 Iu, Qd	Not Reported
Esomeprazole Magnesium	C	Unknown	400 Mg, Bid	Not Reported
Esomeprazole Magnesium	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	Unk	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nasonex	C	Unknown	2 Df, Bid	Not Reported
Nasonex	C	Unknown	Unk, Bid	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Perphenazine	C	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Qd	Not Reported
Trazodone Hydrochloride	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D /00107901/	C	Unknown	400 Unk, Unk	Not Reported

Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	1200 Mg, Bid, 2 Every 1 Day	Not Reported
Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Mg, Q.M.T.	Not Reported
Risedronate Sodium	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Mg, Q.Wk.	Not Reported
Cholecalciferol	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Vitamin B6	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

	Cyanocobalamin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	13242895	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1876032-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Joint Swelling; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	13254993	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006561		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic	Fentanyl			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Apo-Gabapentin			S	Oral	100 Mg, Q.O.Wk.		Apotex
	Nortriptyline			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Apotex
	Celecoxib			S				Apotex
	Actemra			S	Intravenous (not otherwise specified)	488 Mg,Once Every Four Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.I.W		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	75 Mg, Once Every 4 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, (Once Every Four Days)		Not Reported

Product Effect Decreased; Treatment Failure	Orencia	S	Subcutaneous	1 Df, Q.Wk.	Not Reported
	Oxycontin	S	Unknown	750 Mg, Q.M.T.	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Sulfasalazine	S	Oral	2.5 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, (One Every Three Weeks)	Not Reported
	Myochrysine	S	Intramuscular	60 Mg, Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Calcium	C	Unknown	Unk, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Gabapentin	C	Oral	100 Mg, Bid	Not Reported
	Genteal /00445101/	C	Unknown		Not Reported
	Lomotil /00034001/	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Unknown	2 Df, Bid	Not Reported
	Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Q.H.	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Gbq, Q.H.	Not Reported
	Omega 3 /01334101/	C	Unknown	1200 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	5 Mg, 1 Every 2 Hours	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Q.H.	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Q.H.	Not Reported
	Vitamin D /00107901/	C	Unknown		Not Reported

D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Acetaminophen	C	Oral	1000 Mg, Qd	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Risedronate Sodium	C	Unknown	36 Mg, Q.Wk.	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Omega 3 /06852001/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Q.H.	Not Reported
Fentanyl	C	Unknown	Unk	Not Reported
Fish Oil	C	Unknown	Unk	Not Reported
Omega 3-6-9 /01333901/	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Genteal /06684801/	C	Unknown	Unk	Not Reported
Zoledronic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	13929657	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2687		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Drug Ineffective; Drug Intolerance;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Gastrointestinal Disorder;	Enbrel			S	Unknown			Not Reported
Immobile; Lymphadenopathy;	Sulfasalazine			S	Unknown			Not Reported

Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	13932844	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017133050		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Cardiac Failure; Cytopenia; Generalised Oedema; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Prednisone			C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	14235931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3893		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported

Minocycline	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous drip		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Apo-Minocycline	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Leflunomide	C	Unknown	20 Unk	Not Reported
Leflunomide	C	Unknown		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported
Hydroxychloroquine	C	Subcutaneous		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported
Amoxil	C	Unknown		Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)		Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)		Not Reported
Bcg Vaccine	C	Unknown		Not Reported

	Gold	C	Unknown	Not Reported
	Clavulin	C	Unknown	Not Reported
	Clavulin	C	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulante Potass	C	Unknown	Not Reported
	Adalimumab	C	Unknown	Not Reported
	Risedronate	C	Oral	Not Reported
	Amoxicillin	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	15218809	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1004		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Arthralgia; Arthropathy;	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
Blood Creatinine Decreased; Blood	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Pressure Diastolic Decreased; C-Reactive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Protein Increased; Contraindicated Product	Methotrexate (Trade Name Unknown)			S	Intra-arterial			Not Reported
Administered; Contusion; Discomfort; Drug	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Ineffective; Drug Intolerance; Duodenal	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
Ulcer Perforation; Fatigue; General Physical Health	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Deterioration; Glossodynia; Hand	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Deformity; Heart Rate Decreased; Helicobacter	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Infection; Hepatic Enzyme								

Increased; Hip Arthroplasty;	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
Hypersensitivity; Joint Swelling; Knee	Methotrexate (Trade Name Unknown)	S	Parenteral	Not Reported
Arthroplasty; Live Birth; Malignant Melanoma;	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
Maternal Exposure During Pregnancy; Monocyte	Enbrel	S	Subcutaneous	Not Reported
Count Increased;	Enbrel	S	Oral	Not Reported
Musculoskeletal Disorder;	Enbrel	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Enbrel	S	Unknown	Not Reported
Neutrophil Count	Enbrel	S	Subcutaneous	Not Reported
Increased; Off Label Use;	Enbrel	S	Subcutaneous	Not Reported
Pain; Pemphigus;	Enbrel	S	Unknown	Not Reported
Pericarditis; Product Complaint; Product Use	Enbrel	S	Unknown	Not Reported
Issue; Rash; Red Blood	Enbrel	S	Subcutaneous	Not Reported
Cell Sedimentation Rate Increased; Rheumatoid	Enbrel	S	Subcutaneous	Not Reported
Arthritis; Rheumatoid	Enbrel	S	Unknown	Not Reported
Factor Positive;	Enbrel	S	Unknown	Not Reported
Seborrhoeic Keratosis;	Enbrel	S	Subcutaneous	Not Reported
Sinusitis; Swelling;	Enbrel	S	Unknown	Not Reported
Synovial Disorder;	Folic Acid	S	Unknown	Not Reported
Synovitis; Systemic Lupus Erythematosus;	Folic Acid	S	Unknown	Not Reported
Therapeutic Product Effect Decreased; Therapeutic	Folic Acid	S	Oral	Not Reported
Product Effect Incomplete;	Folic Acid	S	Unknown	Not Reported
Treatment Failure; Wound	Fosamax	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Subcutaneous	Not Reported
	Fosamax	S	Intracavernous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported

Humira	S	Subcutaneous	Cyclic	Not Reported
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported

Actemra	S	Subcutaneous	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Oral		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown	5mg/5 Ml	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported

Diclofenac Sodium	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Unknown		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Other		Not Reported
Apo-Sulfasalazine	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Golimumab	S	Intravenous (not otherwise specified)		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Stelara	S	Subcutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Oral		Not Reported
Hydrocortisone Acetate	S	Other		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Zyrtec	S	Unknown	5 Mg/5ml	Not Reported

Zyrtec	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown	10 (Units Unknown)	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Diclofenac	C	Unknown		Not Reported
Ibuprofen	C	Unknown		Not Reported
Lisinopril	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Omega	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

Vitamin C	C	Unknown	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported
Omeprazole Sodium	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Acetaminophen	C	Oral	Not Reported
Acetaminophen	C	Oral	Not Reported
Curamin	C	Unknown	Not Reported
Diphenhydramine Hcl	C	Oral	Not Reported
Leucovorine	C	Unknown	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Vitamin C	C	Unknown	Not Reported
Leflunomide	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	15733141	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1974607-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling; Therapeutic	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

Product Effect Decreased	Plaquenil	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Haemophilus Influenzae	C		Not Reported
	Prevnar 13	C	Intramuscular	Not Reported
	Tetanus Vaccine	C	Unknown	Not Reported
	Hydroxychloroquine	C		Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pneumococcal Vaccine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	16142642	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027732		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	16472913	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1957		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17660087	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145806		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Celebrex			S	Unknown	200 Mg, 1x/Day		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Parenteral	Unk		Pfizer

Xeljanz	S	Oral	10 Mg, 1x/Day		Pfizer
Xeljanz	S	Oral	5 Mg, 2x/Day		Pfizer
Xeljanz	S		10 Milligram, Qwk (2 Days)		Pfizer
Atorvastatin Calcium	S	Unknown	Unk		Pfizer
Rituximab	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Azathioprine	S		Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Hydroxychloroquine Sulfate	S		Unk		Not Reported
Leflunomide	S		Unk		Not Reported
Orencia	S		Unk		Not Reported
Cannabis Sativa	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	7 Mg, 1x/Day		Not Reported
Thyroid	C	Unknown	Unk		Not Reported
Tofacitinib	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17668878	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1723		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Anaemia; Angioedema; Asthenia; Blister;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Diarrhoea; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Intolerance; Dyspnoea; Feeling Abnormal; Feeling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Drunk; Gastrointestinal Disorder; Hepatic Enzyme	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Abnormal; Hypoaesthesia; Inappropriate Schedule Of Product Administration; Migraine; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Pharyngeal Swelling; Psoriatic Arthropathy; Pyrexia; Swelling Face; Synovitis; Uveitis	Sulfasalazine	S	Unknown	Not Reported
	Lipitor	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Arthrotec	S	Unknown	Not Reported
	Arthrotec	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Dovobet	C	Topical	Not Reported
	Flovent	C	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Multi Vitamins & Minerals	C	Oral	Not Reported
	Omeprazole	C	Oral	Not Reported
	Omeprazole	C	Oral	Not Reported
	Ventolin	C	Unknown	Not Reported
	Ventolin	C	Unknown	Not Reported
	Vitamin D2	C	Unknown	Not Reported
	Vitamin D2	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17682764	EXPEDITED (15-DAY)		OT	CA-SAMSUNG			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Unknown			Not Reported

Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown. Solution Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
Folic Acid	C	Unknown		Not Reported
Piroxicam	C	Unknown	Unknown	Not Reported
Prednisone	C	Oral	Unknown	Not Reported

	Tofacitinib Citrate	C	Unknown	Unknown		Not Reported
	Xeljanz	C	Oral			Not Reported
	Leflunomide	C	Unknown	Unknown		Not Reported
	Leflunomide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17746154	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010471		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Leflunomide			S	Unknown	20 Mg, Q.Wk.		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	9 Mg, Unk		Apotex
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	9 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Infliximab			S	Oral	5 Mg, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Q.Wk.		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	9 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk, Q.M.T.		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

Acetaminophen	C	Unknown	500 Mg, Unk		Not Reported
Cetirizine Hydrochloride	C	Unknown	10 Mg, Qd		Not Reported
Gabapentin	C	Unknown	600 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17796741	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123205			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Arava			S	Unknown	Unk		Sanofi
	Acetylsalicylic Acid			S	Unknown	325 Mg		Not Reported
	Diclofenac Sodium			S	Topical	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			S		Unk		Not Reported
	Diclofenac Sodium			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S		Unk		Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17798804	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123322			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	300 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17878302	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3435752-00		65 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Kaletra 200/50			S	Oral			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17954251	EXPEDITED (15-DAY)		LT, OT	ES-HETERO-HET2020ES00679		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Disorientation; Hyperbilirubinaemia; Liver Function Test Abnormal; Urinary Retention	Levofloxacin			S	Unknown	500 Mg, Bid Every 12 Hours		Hetero
	Hidroxicloroquina /00072601/			S	Oral	800 Mg 1 Day + 400 Mg The Rest		Not Reported
	Lopinavir + Ritonavir			S	Unknown	Dose Of 200/20 Four Times A Day		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Urbason /00049601/			C	Unknown	Unk		Not Reported
	Pulmicort			C	Unknown	Unk		Not Reported
	Ventolin /00139501/			C	Unknown	Unk		Not Reported
	Clexane			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18023425	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Prednisone			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Form Of Admin: Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18082550	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020ES210932		75 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eczema; Eosinophilia; Face Oedema; Leukocytosis; Neutrophilic Dermatosis; Off Label Use; Product Use In Unapproved Indication; Rash Erythematous; Rash	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis

Pruritic; Rash Pustular;
Skin Oedema

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18089285	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-036647		78 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Drug Ineffective For Unapproved Indication; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Azithromycin			S				Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102173	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3506623-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Febrile Neutropenia; Leukopenia	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102223	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020122858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue;	Otezla			S	Unknown	Unk		Amgen
	Cosentyx			S	Oral	300 Milligram, Qmo		Not Reported

Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Diclofenac	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Leucovorin Calcium	S	Oral	5 Milligram, Qwk	Not Reported
	Meloxicam	S	Oral	7.5 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	4 Dosage Form, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Pantoprazole	S	Oral	1 Dosage Form, Qd	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Synthroid	S	Unknown		Not Reported
	Tramadol Hydrochloride	C		Unk Unk, Qd	Not Reported
	Premarin	C			Not Reported
	Salbutamol	C	Unknown		Not Reported
	Diltiazem Hydrochloride	C	Oral	240 Milligram	Not Reported
	Fluticasone Propionate	C	Unknown		Not Reported
	Mar-Pantoprazole	C		Unk	Not Reported
	Mometasone Furoate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102459	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Sulfasalazine	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Simponi	S	Subcutaneous	Not Reported
Actemra	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Cimzia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported
Bupropion	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102501	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807835			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102509	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807817		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102559	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1809843		50 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Drug Interaction; Off Label Use; Respiratory Failure	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S				Not Reported
	Hydroxychloroquine			S	Oral	800 Milligram Daily;		Teva
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Thymoglobulin			S	Unknown			Not Reported
	Everolimus			S	Unknown			Not Reported
	Everolimus			S				Not Reported
	Prednisone			S	Unknown	5 Milligram Daily;		Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Interferon-Beta			S	Subcutaneous			Not Reported
	Losartan			C	Unknown	100 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Meropenem			C	Unknown			Not Reported

	Meropenem	C			Not Reported
	Norepinephrine	C	Unknown		Not Reported
	Ceftaroline	C	Unknown		Not Reported
	Ceftaroline	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102818	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807472			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	1800 Milligram Daily;		Not Reported
	Premarin			C	Unknown			Not Reported
	Tylenol			C	Unknown	1300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102846	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102847	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807822		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807550		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102875	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807843		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex [Orphenadrine Citrate]			C				Not Reported
	Omnaris			C	Unknown			Not Reported

	Pantoprazole Sodium Anhydrous	C		Not Reported
	Plantago Ovata	C		Not Reported
	Synthroid	C		Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102886	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102891	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808388		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Potassium Chloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102892	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102912	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102923	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807512		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102924	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis;	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Vomiting	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102990	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807524		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Stomatitis; Swelling; Synovitis; Tenderness	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Loperamide	C	Unknown	Not Reported
	Norflex[Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18102997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807521		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103012	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807839		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103029	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1807510		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection;	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported

Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram Daily;	Not Reported
	Isoniazid		S	Unknown		Not Reported
	Myochrysine		S	Intramuscular		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Unknown		Not Reported
	Sulfasalazine		S	Oral	2000 Milligram Daily;	Not Reported
	Varicella Zoster Immune Globulin Human		S	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103030	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807574		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Orencia			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C	Unknown	7 Milligram Daily;		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103495	NON-EXPEDITED		HO	US-STRIDES ARCOLAB LIMITED-2020SP001099		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptosporidiosis Infection; Diarrhoea; Hypogammaglobulinaemia; Leukopenia; Neutropenia; Off Label Use; Tachycardia; Weight Decreased	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103731	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1068801		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Covid-19; Off Label Use; Respiratory Failure; Stress Cardiomyopathy	Prednisone			S	Unknown	Unk		Mylan
	Prednisone			S	Unknown	Initially Dose Reduced To 30mg, Eventually Discontinued		Mylan
	Tacrolimus			S	Unknown	Initially Continued With Any Change In Dose (Unknown Route)		Mylan
	Tacrolimus			S		Later Changed To Continuous Infusion During Hospitalisation		Mylan
	Mycophenolate Mofetil			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			S	Unknown	Initially Dose Was Reduced By 50%		Mylan
	Mycophenolate Mofetil			S	Unknown	Eventually Discontinued; Re-Started After Final Discharge		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

	Basiliximab	S	Unknown		Mylan
	Tocilizumab	S	Intravenous (not otherwise specified)	400 Milligram, Total Single Dose	Mylan
	Azithromycin	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104005	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807520		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rho D Immune Globulin Human			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous	10 Milligram Daily;		Not Reported
	Celebrex			C	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Lipitor			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104007	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807530			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Methotrexate			S	Unknown			Barr

Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Apo-Prednisone		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104052	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807557		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104283	EXPEDITED (15-DAY)		LT	PT-TEVA-2020-PT-1808185		66 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	200mg 2x / Day, Unit Dose: 400 Mg		Teva
	Enalapril			C				Not Reported
	Colecalciferol			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Betahistine			C				Not Reported
	Alfacalcidol			C				Not Reported
	Sertraline			C				Not Reported
	Folic Acid			C				Not Reported
	Sevelamero Teva			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104671	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX015690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified		Baxter
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18105038	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020029683		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Ev 2		Not Reported

				Weeks(Qow)	
Hydroxychloroquine Sulfate		S			Not Reported
Hydroxychloroquine Sulfate		S	Subcutaneous	40 Milligram	Not Reported
Kevzara		S			Not Reported
Orencia		S			Not Reported
Methotrexate		S		10 Milligram	Not Reported
Methotrexate		S		20 Milligram	Not Reported
Methotrexate		S	Oral		Not Reported
Methotrexate		S	Subcutaneous		Not Reported
Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab		S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Simponi		S	Subcutaneous		Not Reported
Sulfasalazine		S			Not Reported
Tocilizumab		S		Unk	Not Reported
Tofacitinib		S			Not Reported
Xeljanz		S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Prednisone		C		10 Milligram	Not Reported
Rabeprazole Sodium		C	Oral	20 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18105245	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1808241		79 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Covid-19 Treatment; Gamma-Glutamyltransferase Increased; Hepatotoxicity	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported
	Plaquinol			S	Oral	400mg 12 / 12h In D0		Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported
	Levofloxacin			C	Intravenous (not otherwise specified)			Not Reported
	Ipratropium Bromide			C	Respiratory			Not Reported

			(inhalation)		
	Haloperidol Ratiopharm 5 Mg/Ml Solucao Injectavel	C	Intramuscular		Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)		Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)		Not Reported
	Omeprazole	C	Oral		Not Reported
	Sodium Chloride	C	Intravenous (not otherwise specified)	2000 Ml In D0	Not Reported
	Salbutamol	C	Respiratory (inhalation)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18105296	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809096		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18105588	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808613		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Leucovorin [Folinic Acid]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18105713	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809331		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18105932	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808616			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease;	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported

Joint Swelling; Musculoskeletal Stiffness	Imuran	S	Unknown	100 Milligram Daily;	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Glyburide	C	Unknown	750 Milligram Daily;	Not Reported
	Lipitor	C	Unknown	10 Milligram Daily;	Not Reported
	Metformin	C	Oral		Not Reported
	Mycophenolate Mofetil	C	Oral	1500 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106256	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808392		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Product Use In Unapproved Indication; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram Daily;		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106279	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1808380		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Ilaris Single-Use Vial			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106302	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808465		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	400 Milligram Daily;		Not Reported

Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Ativan	C			Not Reported
	Benadryl	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Darifenacin Hydrobromide	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Furosemide	C			Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C			Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown		Not Reported
	Lasix [Furosemide]	C	Unknown		Not Reported
	Morphine Sulfate	C	Unknown		Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown		Not Reported

Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106999	NON-EXPEDITED		HO	US-PFIZER INC-2020292140			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Fatigue; Hypertension; Lethargy; Malaise; Pruritus; Skin Haemorrhage; Speech Disorder; Swollen Tongue; Urticaria	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18107264	NON-EXPEDITED		OT	CA-AMGEN-CAN-20180803503		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Otezla			S	Oral	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram, 185 Days		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 4 Years		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported

	Hydroxychloroquine Sulfate		S	Subcutaneous	400 Milligram	Not Reported
	Certolizumab Pegol		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18107266	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809040		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Methotrexate			S	Unknown	20 Mg		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1600 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	8 Gram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18107298	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809081			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Nephrolithiasis; Product Dose Omission; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown	150 Mg		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18107904	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18107906	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808598			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18108554	EXPEDITED (15-DAY)		OT	CA-ACCORD-193770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Humira	S	Subcutaneous	Subcutaneous Solution, 1 Every 1 Weeks		Not Reported
Aurothioglucose	S	Unknown			Not Reported
Enbrel	S	Unknown	1 Every 1 Weeks		Not Reported
Cimzia	S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe, 1 Every 1 Weeks		Not Reported
Ciclosporin	S	Unknown			Not Reported
Certolizumab	S	Unknown			Not Reported
Azathioprine	S	Unknown			Not Reported
Arava	S	Oral			Not Reported
Actemra	S	Unknown			Not Reported
Humira	S	Subcutaneous	1 Every 1 Weeks		Not Reported
Enbrel	S	Unknown			Not Reported
Azathioprine	S	Unknown			Not Reported
Actemra	S	Unknown	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18108556	EXPEDITED (15-DAY)		OT	CA-ACCORD-193768		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	Subcutaneous Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution, 1 Every 2 Weeks	Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Tenofovir	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18108572	EXPEDITED (15-DAY)		OT	CA-ACCORD-193769		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate			S	Oral			Accord
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Subcutaneous Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18108577	EXPEDITED (15-DAY)		OT	CA-ACCORD-193773		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Arava			S	Unknown	2 Every 2 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	14185631	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170118		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen

Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Anakinra		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Warfarin		S	Unknown	Unk	Not Reported
	Celebrex		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Warfarin Sodium		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	14191056	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490913		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Plaquenil		S	Unknown	Unk	Not Reported
	Warfarin		S	Unknown	Unk	Not Reported
	Warfarin Sodium		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	15629333	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ABBVIE-18K-028-2557519-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Foa-Solution		Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Infliximab	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	15788090	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0212		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Twice A Week		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	2 Times/Week		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous	Cyclic (Every 2 Weeks)		Not Reported
	Humira			S	Subcutaneous	Cyclic		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Cyclic		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Anakinra	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Etanercept	S	Subcutaneous	2 Times/Week	Not Reported
Azathioprine	S	Unknown		Not Reported
Azathioprine	S	Oral		Not Reported
Azathioprine	S	Oral		Not Reported
Gold	S	Intramuscular		Not Reported
Wellbutrin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	15934107	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655644-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Imuran			C	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17423283	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-00169		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria Acute	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17596953	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068456			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		15 Mg, Qw		Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Actemra			S		567 Mg, Qm		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17664282	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1701		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown	10 Milligram, Qwk (2 Days)		Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported

Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Azathioprine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Cannabis Sativa	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Thyroid	C	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17677151	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Arava			S	Endocervical	20 Mg		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	567 Mg, Q4w (Every 1 Month)		Not Reported

	Rituxan	S	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Inflectra [Infliximab]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17727246	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010388		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Tramacet			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17793016	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123056			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Interstitial Lung Disease; Vomiting	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17796745	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123222			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Arava			S	Oral	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2 Every 1 Day		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg, 1 Every 1 Day		Not Reported
	Sulfasalazine			S		1000 G, 2 Every 1 Day		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S		20 Mg, 1 Every 1 Day		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17865792	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA142257			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Weight Decreased	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Prednisone			S	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	17976386	EXPEDITED (15-DAY)		OT	AU-ABBVIE-20K-008-3469057-00		72 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Graft Versus Host Disease In Skin; Incorrect Dose Administered; Off Label Use	Imbruvica			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Sirolimus			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mabthera			S	Unknown			Not Reported
	Lamotrigine			C				Not Reported
	Quetiapine			C				Not Reported
	Bactrim Ds			C				Not Reported
	Valaciclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18006900	EXPEDITED (15-DAY)		OT	CA-ACCORD-189578		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Methotrexate			S	Unknown			Accord
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Arava	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Elavil	C	Unknown	Not Reported
Paracetamol	C		Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Imitrex	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Sumatriptan	C	Unknown	Not Reported
Tenormin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18065580	EXPEDITED (15-DAY)		HO	CA-ACCORD-191980		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord
	Actemra			S				Not Reported
	Arava			S		Frequency: 1 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Isoniazid			S				Not Reported
	Myochrysine			S	Intramuscular	Frequency: 1 Every 1 Weeks, Dosage Form: Solution Intramuscular		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Dosage For: Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Oral	Frequency: 2 Every 1 Days		Not Reported

	Varicella Virus Vaccine/Live	S	Intramuscular		Not Reported
	Hydroxychloroquine	S	Oral	Frequency:1 Every 1 Days	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18095280	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200737045			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Fibrillation	Darunavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ritonavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18104788	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808610		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18104838	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105141	EXPEDITED (15-DAY)		OT	PE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-255830			Unknown	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental			Sun
	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Meropenem			S	Transplacental	Unk		Not Reported
	Oseltamivir			S	Transplacental			Not Reported
	Vancomycin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105142	EXPEDITED (15-DAY)		OT	PE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-255829		41 YR	Female	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Meropenem			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105160	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24123		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous,Unknown		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous,Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105391	EXPEDITED (15-DAY)		HO	CA-ACCORD-193778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Medication Error; Musculoskeletal Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	Frequency: 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105392	EXPEDITED (15-DAY)		HO	CA-ACCORD-193777		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis;	Methotrexate			S	Subcutaneous	Frequency: 1 Every 2 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Weeks		Not Reported
	Anakinra			S	Subcutaneous	Frequency: 1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	Frequency:1 Every 1 Days		Not Reported
	Immunoglobulin G Human			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported

Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Months	Not Reported
	Prednisone	S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Sulfasalazine	S	Oral	Frequency: 1 Every 1 Days	Not Reported
	Triamcinolone	S			Not Reported
	Enbrel	S	Subcutaneous	Frequency: 1 Every 2 Weeks	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Weeks	Not Reported
	Prednisone	S		Frequency: 2 Every 1 Days	Not Reported
	Prednisone	S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Triamcinolone	S	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105394	EXPEDITED (15-DAY)		DS	CA-ACCORD-193789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Methotrexate			S	Oral			Accord
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Gold			S				Not Reported
	Diclofenac			S				Not Reported
	Ciclosporin			S				Not Reported
	Arava			S				Not Reported
	Methotrexate			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105397	EXPEDITED (15-DAY)		OT	CA-ACCORD-193781			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate		S	Intramuscular		Accord
	Xeljanz		S	Oral	2 Every 1 Days	Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Myochrysine		S	Intramuscular		Not Reported
	Hydroxychloroquine		S	Oral	1 Every 1 Weeks	Not Reported
	Enbrel		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Methotrexate		S	Oral	1 Every 1 Weeks	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105399	EXPEDITED (15-DAY)		OT	CA-ACCORD-193790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S				Accord
	Orencia			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105450	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2020-037657		84 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis; Covid-19 Treatment; Hepatocellular Injury	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day(500 Mg/Dia)		Aurobindo
	Plaquinol			S	Oral	Unk(400mg 12/12h Em D0 E Depois 200mg De 12/12h)		Not Reported
	Nifedipine			C	Oral	60 Milligram, Once A Day		Not Reported
	Nolotil			C	Intravenous (not otherwise specified)	4000 Milligram, Once A Day		Not Reported
	Ketorolac			C	Intravenous (not otherwise specified)	30 Milligram, Once A Day(Sos 2)		Not Reported

Enoxaparin Sodium	C	Subcutaneous	120 Milligram, Once A Day		Not Reported
Cefazolin	C	Intravenous (not otherwise specified)	3000 Milligram, Once A Day		Not Reported
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	9000 Milligram, Once A Day		Not Reported
Indapamide	C	Oral	2.5 Milligram, Once A Day		Not Reported
Amiodarone	C	Oral	200 Milligram, Once A Day		Not Reported
Morphine	C	Unknown	2 Milligram, Once A Day(Sos 4)		Not Reported
Sertraline	C	Oral	50 Milligram, Once A Day		Not Reported
Omeprazole	C	Oral	20 Milligram, Once A Day		Not Reported
Oxazepam	C	Oral	15 Milligram, Once A Day		Not Reported
Paracetamol	C	Intravenous (not otherwise specified)	3000 Milligram, Once A Day		Not Reported
Furosemide	C	Intravenous (not otherwise specified)	40 Milligram, Once A Day		Not Reported
Quetiapine	C	Oral	25 Milligram, Once A Day		Not Reported
Candesartan	C	Oral	32 Milligram, Once A Day		Not Reported
Captopril	C	Oral	25 Milligram, Once A Day(Sos 3)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18105796	EXPEDITED (15-DAY)		HO	IE-TEVA-2020-IE-1809894		22 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Diarrhoea; Off Label Use	Etoposide			S	Unknown	Received Four Cycles Of Escbeacopp Regimen		Teva
	Etoposide			S	Unknown	Received Three Cycles Of Ice Regimen		Teva
	Carboplatin			S	Unknown	Received Three Cycles Of Ice Regimen		Not Reported
	Adriamycin			S	Unknown	Received Two Cycles Of		Teva

			Abvd Regimen And Four Cycles Of Escbeacopp Regimen	
Vinblastine	S	Unknown	Received Two Cycles Of Abvd Regimen	Not Reported
Bleomycin	S	Unknown	Received Two Cycles Of Abvd Regimen And Four Cycles Of Escbeacopp Regimen	Not Reported
Dacarbazine	S	Unknown	Received Two Cycles Of Abvd Regimen	Not Reported
Cyclophosphamide	S	Unknown	Received Four Cycles Of Escbeacopp Regimen	Not Reported
Vincristine	S	Unknown	Received Four Cycles Of Escbeacopp Regimen	Not Reported
Procarbazine	S	Unknown	Received Four Cycles Of Escbeacopp Regimen	Not Reported
Prednisolone	S	Unknown	Received Four Cycles Of Escbeacopp Regimen	Not Reported
Ifosfamide	S	Unknown	Received Three Cycles Of Ice Regimen	Not Reported
Brentuximab Vedotin	S	Unknown	Received Three Cycles	Not Reported
Pembrolizumab	S	Unknown	Received Six Cycles; Patient Was Due For Seventh Cycle	Not Reported
Piperacillin/Tazobactam	S	Unknown		Not Reported
Doxycycline	S	Unknown		Not Reported
Lopinavir/Ritonavir	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Azithromycin	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18106065	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-			Unknown	FRA

002448

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Furosemide			S	Unknown	Unk		Ipca
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Tid		Ipca
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107181	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-002456			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Ipca
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported
	Furosemide			S	Unknown	Unk		Ipca
	Mianserin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107223	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-002457			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Ipca
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported
	Furosemide			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107386	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-002461			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Ipca
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107553	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-002463			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Syncope	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Ipca
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107579	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007479			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatitis	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Methotrexate Sodium			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported

	Orencia	C	Unk	Not Reported
	Cortisone	C	Unk	Not Reported
	Iodine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107602	EXPEDITED (15-DAY)		DE, LT, OT	EG-PFIZER INC-2020286859		71 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Myocardial Ischaemia; Off Label Use; Product Use In Unapproved Indication; Pulmonary Embolism; Septic Shock	Zithromax			S	Oral	500 Mg, 1x/Day (Every 24 Hrs)		Pfizer
	Solu-Cortef			S	Intravenous (not otherwise specified)	50 Mg, Cyclic (1 Per 6 Hour)		Pfizer
	Solu-Medrol			S		Unk		Pfizer
	Hydroquine			S	Oral	400 Mg, Every 12 Hrs For 1 Day		Not Reported
	Hydroquine			S	Oral	200 Mg, Every 12 Hrs For The Next 12 Days		Not Reported
	Saline (Sodium Chloride)			S	Intravenous drip	Unk		Not Reported
	Dextrose 5%			S	Intravenous drip	Unk		Not Reported
	Ringer [Calcium Chloride\Magnesium Chloride\Potassium Chloride\Sodium Acetate]			S	Intravenous drip	Unk		Not Reported
	Oseltamivir [Oseltamivir Phosphate]			C	Oral	75 Mg, 1x/Day		Not Reported
	Paracetamol			C		Unk, As Needed		Not Reported
	Clexane			C	Subcutaneous	60 Iu, Cyclic (1 Per 12hrs)		Not Reported
	Zinc			C	Oral	Unk, As Needed		Not Reported
	Vitamin C Acid			C	Oral	Unk, As Needed		Not Reported
	Marevan			C	Oral	3 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107722	EXPEDITED (15-DAY)		OT	US-LUPIN		39 YR	Male	USA

PHARMACEUTICALS INC.-2020-03966

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	9 Milligram, Qd		Not Reported
	Losartan			C	Unknown	25 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18107803	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-002464			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Ipca
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108282	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1069269		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Enoxaparin			S	Subcutaneous	8000 International Unit, Bid		Mylan
	Azithromycin			S	Unknown	250 Milligram, Qd		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd, Three Times Daily		Mylan

	Rocuronium	C		0.6 Milligram/Kilogram, Qh	Mylan
	Norepinephrine	C	Unknown	0.3 Microgram/Kilogram, Qminute	Mylan
	Meropenem	C	Intravenous (not otherwise specified)	Thrice Daily	Mylan
	Linezolid	C	Intravenous (not otherwise specified)	600 Milligram, Bid	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108537	EXPEDITED (15-DAY)		HO, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-255823		69 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Azithromycin			S	Oral	500 Milligram, Daily, On Day 1		Sun
	Azithromycin			S	Oral	250 Milligram, Daily, For The Following Four Days		Sun
	Enoxaparin Sodium			S	Subcutaneous	0.6 Milliliter, Daily		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Ipca
	Methylprednisolone			S	Intravenous (not otherwise specified)	80 Milligram, Bid		Not Reported
	Favipiravir			S	Oral	1600 Milligram, Bid		Not Reported
	Favipiravir			S	Oral	600 Milligram, Bid		Not Reported
	Acetylcysteine			S	Intravenous (not otherwise specified)	300 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108555	EXPEDITED (15-DAY)		DE, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-002399			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Death; Maternal Exposure During Pregnancy	Hydroxychloroquine	S	Unknown	Unk		Ipca
	Ceftriaxone	S	Unknown	Unk		Not Reported
	Azithromycin	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108728	EXPEDITED (15-DAY)		OT	CA-ACCORD-193555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Accord
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108730	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-193681		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Product	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			C				Not Reported

Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108741	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-ACCORD-193701		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108784	EXPEDITED (15-DAY)		HO	DE-TEVA-2020-DE-1808345		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cervicobrachial Syndrome; Diffuse Alopecia; Erythema; Photodermatosis; Radiculopathy	Hydroxychloroquine	S	Unknown	Unk		Teva
	Abatacept	S	Subcutaneous	125 Mg, Qwk		Not Reported
	Thyronajod	C	Unknown			Not Reported
	Acetylsalicylic Acid	C	Unknown			Not Reported
	Dekristol	C	Unknown			Not Reported
	Palexia	C	Unknown			Not Reported
	Nebivolol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108826	EXPEDITED (15-DAY)		HO, OT	DE-ADVANZ PHARMA-202007007492			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Thoracic Vertebral Fracture	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108871	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108873	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1807786		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Blindness Unilateral; Condition Aggravated;	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Enbrel		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108930	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18108948	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808460		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fibromyalgia;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Darifenacin Hydrobromide	C	Unknown		Not Reported
	Dexamethasone	C	Intramuscular		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Furosemide	C	Unknown	120 Milligram Daily;	Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Norflex[Orphenadrinecitrate]	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

	Restasis		C	Unknown	Not Reported
	Synthroid		C	Unknown	Not Reported
	Triamcinolone Acetonide		C	Intra-articular	Not Reported
	Trimethoprim		C	Unknown	Not Reported
	Urispas		C	Unknown	Not Reported
	Vagifem		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109081	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808377		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Liver Function Test Increased; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109118	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808116		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109149	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007502			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Therapy Interrupted	Hydroxychloroquine			S	Unknown			Concordia
	Otezla			S	Oral	30 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109150	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202007007491			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk (Quensyl)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109157	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1808389		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Dyspnoea; Odynophagia; Rheumatoid Arthritis; Stridor	Methotrexate			S	Unknown			Barr
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109168	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808422		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes	Methotrexate			S	Unknown			Barr

Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C		Not Reported
	Synthroid	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109259	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807857		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Asa	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109536	EXPEDITED (15-DAY)		OT	CA-ACCORD-193716			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Intravenous (not otherwise specified)			Accord
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109541	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-193799			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Methotrexate			S				Accord
	Cosentyx			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported

	Otezla	S	Oral			Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Stelara	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18110613	NON-EXPEDITED			US-SLATE RUN PHARMACEUTICALS-20US000246			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin Usp			S	Unknown	400 Milligram, Qd		Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Aspirine			C	Unknown			Not Reported
	Aspirine			C				Not Reported
	Statin [Atorvastatin Calcium]			C	Unknown			Not Reported
	Statin [Atorvastatin Calcium]			C				Not Reported
	Oxygen			C	Nasal	4 Litre Per Minute		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18110854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1807912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18111055	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	12289723	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-LUPIN PHARMACEUTICALS INC.-2016-01536			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril			S	Transplacental	20 Milligram, Qd (From Gestational Week 0-113+6)		Lupin
	Simvastatin Tablets			S	Transplacental	Unk (From Gestational Week 0-14)		Lupin
	Ezetimibe			S	Transplacental	Unk		Not Reported
	Ezetimibe			S	Transplacental	Unk (From Gestational Week 0-14)		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk (From Gestational		Not Reported

			Week 0-14)	
Pantoprazole	S	Transplacental	40 Milligram, Qd (0-13.6 Gestational Week)	Not Reported
Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd (From Gestational Week 0-14)	Not Reported
Xarelto	S	Transplacental	Unk (From Gestational Week 0-5)	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd	Not Reported
Tacrolimus	S	Transplacental	6 Milligram, Qd (From Gestational Week 0-14)	Not Reported
Torasemide	S	Transplacental	100 Milligram, Qd	Not Reported
Salbutamol	S	Transplacental	Unk Unk, Qd ((From Gestational Week 0-14))	Not Reported
Enoxaparin Sodium	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
Nicotine	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
Prednisolone	S	Transplacental	10 Milligram, Bid (From Gestational Week 0-14)	Not Reported
Novaminsulfon	S	Transplacental	Unk (Trimester: First; Probably Only In Hospital In Week 5)	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Metamizole	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
Rituximab	S	Transplacental	Unk (Trimester: Preconceptional)	Not Reported
Heparin Lmw	S	Transplacental	Unk	Not Reported
Aliskiren	S	Transplacental	300 Milligram, Qd (0-4.6 Gestational Week)	Not Reported
Heparin	C	Transplacental	Unk	Not Reported
Cyclophosphamide	C	Transplacental	Unk (3000 [Mg Cumulative]; Preconceptional)	Not Reported

	Mifegyne	C	Transplacental	Unk (13.6 Gestational Week)	Not Reported
	Cytotec	C	Transplacental	Unk (13.6 Gestational Week)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	12701613	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1490		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	2 In 1 Day		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Prednisone Acetate	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Leflunomide	S	Unknown	Cyclical	Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Hcq	C	Unknown		Not Reported
Acetaminophen And Codeine	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Insulin	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Plaquenil	C	Unknown		Not Reported
Plaquenil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	13058399	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015757		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cortisone			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	13182370	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1856140-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis				otherwise specified)	
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Prednisone Acetate		S	Unknown	Not Reported
	Aleve		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Naproxen		S	Oral	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Prednisone Teva		S	Oral	Not Reported
	Plaquenil Sulfate		S	Unknown	Not Reported
	Tocilizumab		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Naproxen Sodium		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	14921684	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044737		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Body Height Below Normal; Bone Density Decreased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Joint Destruction;	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Nausea; Obesity; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Etanercept	S	Subcutaneous	25 Mg, 2 Times/Wk	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Unk	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
	Methotrexate	S	Unknown	15.0 Mg/M2, Unk	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, 2 Times/Wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17812231	EXPEDITED (15-DAY)		DS, OT	MX-ADVANZ PHARMA-202005005296			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Depression; Hypoxia; Intentional Product Misuse; Pleural Effusion; Pyrexia; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17839334	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605480		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Naproxen	C		Not Reported
	Risedronate	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17868875	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609739			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis;	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting				otherwise specified)	
	Prednisone		S	Oral	Not Reported
	Prednisone		S		Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Triamcinolone		S	Unknown	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		S		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Infliximab		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17875500	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011794		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Cyclosporine			S	Oral	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, 1 Every 4 Weeks		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported

Lyrica	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Piroxicam	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17974713	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795666		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Intravenous (not otherwise specified)	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18001546	EXPEDITED (15-DAY)		HO, OT	NVSC2020ES188401		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; C-Reactive Protein Increased; Coronavirus Infection; Drug Interaction; Drug Level Increased;	Mycophenolic Acid			S	Oral	Unk, Bid		Novartis
	Tacrolimus			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	800 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram (0.5 Day)		Not Reported

Gastrointestinal Disorder; Nephropathy Toxic; Off Label Use; Renal Failure	Hydroxychloroquine	S	Oral	200 Milligram (0.5 Day)		Not Reported
	Lopinavir/Ritonavir	S	Oral	1 Df, Qd (200/100mg)		Not Reported
	Envarsus	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18006774	EXPEDITED (15-DAY)		LT, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-252850		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Clonus; Delirium; Depressed Level Of Consciousness; Depressed Level Of Consciousness; Drug Interaction; Encephalopathy; Hyperhidrosis; Hyperreflexia; Hypertension; Myoclonus; Off Label Use; Serotonin Syndrome; Speech Sound Disorder; Tachycardia; Urinary Retention	Lopinavir/Ritonavir			S	Unknown	400/200mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Lithium			S	Unknown	800 Milligram, Daily		Sun
	Duloxetine			S	Unknown	120 Milligram, Daily		Sun
	Haloperidol			S	Unknown	1 Milligram, Bid		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18080583	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020060251			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling;	Prevnar 13			S	Intramuscular	0.5 Mg, Single		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Leucovorin Calcium			S	Unknown	1.0 Dosage Form, Qwk		Pfizer

Off Label Use; Product Use Issue	Depo-Medrol With Lidocaine	S	Intra-articular	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	15 Milligram, Qwk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	162 Milligram, Qwk	Not Reported
	Apo-Prednisone	S	Unknown	1 Mg	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine Sodium	S	Oral	200 Milligram, Qd	Not Reported
	Azathioprine Sodium	S	Oral	200 Mg, 1x/Day	Not Reported
	Humira	S	Subcutaneous	40 Mg, 2x/Week	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	400 Mg, 1x/Day	Not Reported
	Ketoprofen	S	Topical	Unk Unk, Qid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Imuran [Azathioprine]	S	Oral	200 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18085163	EXPEDITED (15-DAY)		DE	NVSC2020PT210396		89 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg, Qd (500mg/Dia)		Novartis
	Plaquinol			S	Oral	400 Mg, Qd (Comprimido)		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Amiodarone			C	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Magnesium Sulfate	C	Intravenous (not otherwise specified)	Unk	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Meropenem	C	Intravenous (not otherwise specified)	Unk	Not Reported
Enoxaparin Sodium	C	Subcutaneous	Unk	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Lactitol	C	Oral	Unk	Not Reported
Calcium Gluconate	C	Intravenous (not otherwise specified)	Unk	Not Reported
Glucose	C	Intravenous (not otherwise specified)	Unk	Not Reported
Human Serum Albumin	C	Intravenous (not otherwise specified)	Unk	Not Reported
Oxazepam	C	Oral	Unk	Not Reported
Potassium Dihydrogen Phosphate	C	Intravenous (not otherwise specified)	Unk	Not Reported
Esomeprazole	C	Intravenous (not otherwise specified)	Unk	Not Reported
Paracetamol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Amoxicilina + Acido Clavulanico	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18094315	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020289182		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Hypertension; Pulmonary Fibrosis	Sulfasalazine		S	2500 Mg, Twice A Day (1500 Mg In The Morning And 1000 Mg In The Afternoon)	Pfizer
	Hydroxychloroquine		S	400 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18095564	NON-EXPEDITED		OT	CA-AMGEN-CAN-20170800931		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Otezla			S	Oral	30 Milligram, Bid		Amgen
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	30 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18103087	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1068857		65 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Off Label Use	Azithromycin			S	Oral	500mg/Dia		Mylan
	Plaquinol			S	Oral	400mg De 12/12h Em D0 E Depois 200mg 12/12h		Mylan
	Enoxaparin Sodium			C	Subcutaneous	20 Milligram, Qd		Mylan
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Qd		Mylan
	Quetiapine			C	Oral	Unk		Mylan
	Esomeprazole			C	Oral	40 Milligram, Qd		Mylan
	Ipratropium Bromide			C	Respiratory (inhalation)	4 Inalacoes 6/6h		Mylan
	Trazodone			C	Oral	50 Milligram, Qd		Mylan

Levothyroxine Sodium	C	Oral	50 Microgram, Qd		Mylan
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	Unk		Mylan
Clonidine	C	Oral	0.15 Milligram, Qd		Mylan
Salbutamol	C	Respiratory (inhalation)	6 Inalacoes 4/4h		Mylan
Escitalopram	C	Oral	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18103434	NON-EXPEDITED		OT	CA-AMGEN-CAN-20190402230		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis; Sleep Disorder	Otezla			S	Oral	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Methotrexate	C	Unknown	Unk		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18111142	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809328		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18111211	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255238		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Lung Infiltration; Platelet Count Decreased; Product Use In Unapproved Indication; Skin Necrosis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Metoprolol			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	2 Gram		Not Reported
	Azithromycin			S	Unknown	500 Milligram		Sun
	Furosemide			S	Unknown	Unk		Sun
	Unfractionated Heparin Infusion			S	Unknown	12 (Units/Kg/H)		Not Reported
	Argatroban			C	Unknown	2 (Microgram/Kg/Min)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18111279	NON-EXPEDITED			US-SA-2020SA201670			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysarthria; Epistaxis; Fatigue; Feeling Abnormal; Hypertension; Insomnia; Joint Swelling; Lethargy; Malaise; Pain; Pruritus; Skin Haemorrhage; Stress; Swollen Tongue; Urticaria	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18111396	EXPEDITED (15-DAY)		HO, OT	ES-CPL-001874		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18111740	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported

Ciclosporin	S	Unknown	Unknown		Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Single-Use Pre-Filled Syringe Solution Subcutaneous		Not Reported
Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112066	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007546			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Below Therapeutic; Systemic Lupus Erythematosus	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112155	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202007007570			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hyponatraemia; Red Blood Cell Count Decreased; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112156	EXPEDITED (15-DAY)		OT	CA-ACCORD-193960		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal;	Methotrexate			S				Accord
Condition Aggravated;	Mycophenolic Acid			S				Accord

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Pregabalin	S			Not Reported
	Tocilizumab	S		1 Every 4 Weeks	Not Reported
	Arava	S	Oral	1 Every 1 Weeks	Not Reported
	Azathioprine	S			Not Reported
	Certolizumab	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Ciclosporin	S			Not Reported
	Cimzia	S	Subcutaneous	1 Every 1 Weeks, Solution For Injection In Pre-Filled Syringe	Not Reported
	Enbrel	S		1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Hydroxychloroquine	S			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Rituximab	S			Not Reported
	Simponi	S			Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112159	EXPEDITED (15-DAY)		HO	CA-ACCORD-193974		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Methotrexate			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S	Unknown	Not Specified		Not Reported
	Tacrolimus			S	Unknown	1 Every 1 Days		Accord
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	S	Unknown	Not Specified		Not Reported
Prednisone	C	Oral	Not Specified, 1 Every 1 Days		Not Reported
Tacrolimus	S	Unknown	1 Every 1 Days		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112200	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1809893		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysbiosis; Liver Injury; Off Label Use; Pneumatosis Intestinalis	Piperacillin W/Tazobactam			S	Unknown	Dose: 4.5g Three Times Daily		Not Reported
	Amoxicillin Clavulanate			S	Unknown			Teva
	Lactulose			S	Unknown	Dose: Average Dose Of 25ml Per Day		Teva
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Teicoplanin			S	Intravenous (not otherwise specified)	Loading Dose Unknown		Not Reported
	Enoxaparin			S	Subcutaneous	4000ui		Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112298	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04083		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Lupin
	Azithromycin			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112357	EXPEDITED (15-DAY)		HO, LT, OT	BE-LUPIN PHARMACEUTICALS INC.-2020-04105		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Glucose-6-Phosphate Dehydrogenase Deficiency; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112373	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-04112		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Off Label Use	Methylprednisolone			S	Intravenous (not otherwise specified)			Lupin
	Azithromycin			S	Unknown			Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Cyclosporine			S				Not Reported
	Cyclosporine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112391	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-037641		11 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Child Abuse; Drug Dependence; Respiratory Depression	Aripiprazole			S	Oral	2 Milligram, 3 Times A Day		Aurobindo
	Celecoxib			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Fluoxetine			S	Oral	20 Milligram, Once A Day		Aurobindo
	Gabapentin			S	Oral	600 Milligram, 3 Times A Day		Aurobindo
	Pantoprazole			S	Oral	40 Milligram, Once A Day		Aurobindo
	Ascorbic Acid			S	Oral	1500 Milligram, Once A		Not Reported

			Day	
Baclofen	S	Oral	20 Milligram, 3 Times A Day	Not Reported
Bisacodyl	S	Oral	5 Milligram, Once A Day (Prn)	Not Reported
Clobazam	S	Oral	20 Milligram, Two Times A Day	Not Reported
Clonidine	S	Oral	0.05 Milligram, Once A Day (Morning)	Not Reported
Clonidine	S	Oral	0.1 Milligram, Once A Day (Evening)	Not Reported
Colecalciferol	S	Oral	2000 Units, Daily	Not Reported
Dimenhydrinate	S	Oral	20 Milligram, Once A Day (Prn)	Not Reported
Diphenhydramine	S	Oral	12.5 Milligram, Four Times/Day	Not Reported
Docosahexaenoic Acid	S			Not Reported
Fluticasone Propionate	S		250 Microgram, Daily (2 Puffs)	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Once A Day	Not Reported
Hydromorphone	S	Unknown	Unk	Not Reported
Ketorolac	S	Oral	20 Milligram, Four Times/Day (If Necessary)	Not Reported
Leuprorelin	S	Intramuscular	7.5 Milligram Every Month	Not Reported
Lorazepam	S	Sublingual	0.5 Milligram Prn	Not Reported
Lorazepam	S	Sublingual	2 Milligram Prn	Not Reported
Methadone	S	Oral	2 Milligram, 3 Times A Day	Not Reported
Methocarbamol;Paracetamol	S	Oral	900 Milligram, Once A Day (400/500 Mg)	Not Reported
Montelukast	S	Oral	10 Milligram, Once A Day	Not Reported
Phenobarbital	S	Oral	30 Milligram, Two Times A Day	Not Reported
Polyethylene Glycol	S	Oral	30 Milligram, Two Times A	Not Reported

				Day	
	Ranitidine	S	Oral	150 Milligram, Once A Day	Not Reported
	Salbutamol	S		100 Microgram, Every Four Hour (2 Puffs)	Not Reported
	Melatonin	S	Oral	10 Milligram At Night Prn	Not Reported
	Omega 3	S	Oral	200-400-1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112483	EXPEDITED (15-DAY)		OT	CA-ACCORD-193123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Accord
	Tocilizumab			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported

Etanercept	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112484	EXPEDITED (15-DAY)		HO	GB-ACCORD-193819		44 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Palpitations	Hydroxychloroquine			S	Oral			Not Reported
	Verbascum Spp.			C				Not Reported
	Selenium			C				Not Reported
	Docosahexanoic Acid/Eicosapentaenoic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112894	EXPEDITED (15-DAY)		LT, OT	CA-ACCORD-193943		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Iron Decreased; Blood Pressure Increased; Headache; Interstitial Lung Disease; Joint Swelling; Monocyte Count Increased; Muscle Spasms; Off Label Use; Osteoporosis; Oxygen Saturation Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Walking Aid User	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Paracetamol			C	Oral			Not Reported
	Accupril			C				Not Reported
	Apo-Atorvastatin			C				Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Apo-Zopiclone			C				Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Gabapentin			C				Not Reported

	Lactaid	C			Not Reported
	Lactulose	C			Not Reported
	Levemir	C			Not Reported
	Methadone	C			Not Reported
	Methylprednisolone	C			Not Reported
	Nabilone	C			Not Reported
	Novorapid	C			Not Reported
	Pantoprazole	C			Not Reported
	Pms-Cetirizine	C			Not Reported
	Mycophenolic Acid	S	Unknown		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112919	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-193944		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased	Furosemide			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S		2 Every 1 Days, Not Specified		Accord
	Rosuvastatin			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown	Not Specified		Not Reported
	Plaquenil			S	Unknown	2 Every 1 Days		Not Reported
	Prednisone			S	Unknown	Not Specified 1 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Ceftazidime/Ceftazidime Pentahydrate			S	Unknown	Powder For Solution		Not Reported
	Paracetamol			C	Unknown			Not Reported
	Amiodarone			C	Unknown			Not Reported
	Apo-Ketorolac			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Escitalopram			C	Unknown			Not Reported
	Humalog			C	Intravenous (not			Not Reported

Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased			otherwise specified)		
	Hydrochlorothiazide	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Januvia	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Methylprednisolone	C	Unknown		Not Reported
	Metoprolol	C	Unknown		Not Reported
	Pantoloc	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Potassium	C	Unknown		Not Reported
	Risedronic Acid	C	Unknown		Not Reported
	Slow-K	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Ventolin	C	Unknown	Not Specified	Not Reported
	Risedronic Acid	C	Unknown	Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113009	EXPEDITED (15-DAY)		OT	CA-ACCORD-193918		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Retinal Toxicity	Mycophenolic Acid			S		2 Every 1 Days		Accord
	Hydroxychloroquine			S		1 Every 24 Hours		Not Reported
	Prednisone			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			C	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			C		1 Every 24		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113010	EXPEDITED (15-DAY)		OT	CA-ACCORD-193920			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S	Unknown			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113071	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04041			Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use Issue	Vancomycin			S	Intravenous (not otherwise specified)	36 Milligram, Tid (Every 8 Hour)		Lupin

Cefotaxime	S	Intravenous (not otherwise specified)	180 Milligram, Bid (Every 12 Hour) Injection		Lupin
Oseltamivir Phosphate Capsules	S	Unknown	Unk		Lupin
Hydroxychloroquine Sulfate Tablets	S	Unknown	20 Milligram, Qd		Lupin
Azithromycin	S	Oral	100 Milligram, Qd (Syrup)		Lupin
Ranitidine	C	Unknown	75 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113134	EXPEDITED (15-DAY)		OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255601		26 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Azithromycine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Infliximab			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Oral	Unk		Mutual
	Cyclosporine			S	Intravenous (not otherwise specified)	2 Milligram/Kilogram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113216	EXPEDITED (15-DAY)		OT	CA-ACCORD-193766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported

Etanercept	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
Hydroxychloroquine	S	Oral	1 Every 1 Days		Not Reported
Orencia	S	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Prednisone	C	Oral			Not Reported
Leflunomide	C	Unknown			Not Reported
Folic Acid	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113961	EXPEDITED (15-DAY)		DE	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255185		67 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Hydroxychloroquine			S	Unknown	Unk		Sun
	Lopinavir/Ritonavir			S				Not Reported
	Methylprednisolone			S				Not Reported
	Enoxaparin Sodium			S	Subcutaneous	50 International Unit, Daily		Not Reported
	Acetylsalicylic Acid			C		100 Milligram, Daily		Not Reported
	Tocilizumab			C				Not Reported
	Sodium Heparin			C	Intravenous (not otherwise specified)	1000 International Unit, 1dose/Hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18114071	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007449			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18115903	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1809090		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Methotrexate			S	Subcutaneous	1 Every 1 Week		Barr
	Fentanyl			S	Unknown			Cephalon
	Actemra			S	Intravenous (not otherwise specified)	16.2667 Milligram Daily;		Not Reported
	Apo-Gabapentin			S	Oral	200 Milligram Daily;		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	25 Milligram Daily;		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	500 Milligram Daily;		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C	Unknown	2400 Milligram Daily;		Not Reported
	Ergocalciferol			C	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown	300 Milligram Daily;		Not Reported
	Loperamide Hydrochloride			C	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported
	Oxycodone Terephthalate			C				Not Reported
	Pantoprazole Magnesium			C	Unknown	40 Milligram Daily;		Not Reported

Prednisone	C	Unknown	5 Milligram Daily;		Not Reported
Risedronate Sodium	C	Unknown			Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram Daily;		Not Reported
Tylenol	C	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18116497	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertensive Urgency; Presyncope	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18116499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808588		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Asa	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Lantus	C	Subcutaneous	Not Reported
Lozide	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18116527	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1808592		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown	40 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported

Potassium Chloride	C	Unknown	1500 Milligram Daily;		Not Reported
Valsartan	C	Unknown	320 Milligram Daily;		Not Reported
Xalatan	C	Ophthalmic	50 Microgram Daily;		Not Reported
Zingiber Officinale	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18116537	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809046		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Aspirin[Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18116581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809098		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Celecoxib			C	Oral	40 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18116648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809217		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	11868391	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1524163-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	12774241	EXPEDITED (15-DAY)		HO	NL-TEVA-693422ACC		57 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Sulfasalazine			S	Oral	2 Times A Day 4 Piece (S), Extra Info: 500mg		Actavis
	Methotrexaat			S	Oral	Additional Info: 25mg Weekly		Barr
	Plaquenil			S	Oral	200 Milligram Daily; Additional Info: 200mg, Therapy End Date : Asked But Unknown		Not Reported
	Etanercept			S	Subcutaneous	Additional Info: 50mg,		Not Reported

				Therapy End Date : Asked But Unknown	
	Lisinopril	C	Oral	10 Milligram Daily; Additional Info: 10mg, Therapy End Date : Asked But Unknown	Not Reported
	Bisoprolol	C	Oral	10 Milligram Daily; Additional Info: 10mg, Therapy End Date : Asked But Unknown	Not Reported
	Pantozol	C	Oral	40 Milligram Daily; Additional Info: 40mg, Therapy End Date : Asked But Unknown	Not Reported
	Triamtereen/Hct	C	Oral	1 Dosage Forms Daily; Additional Info: 50/4, Therapy End Date : Asked But Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	13058523	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015797		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	14198960	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3659		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	14788235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108819		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Celecoxib		S	Oral	Not Reported
	Celecoxib		S	Oral	Not Reported
	Celecoxib		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Toradol		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Tramadol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	15622445	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557344-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Used Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Unknown	486.0 (Units Not Specified)	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Infliximab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	Enteric Coated	Not Reported
Abatacept	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Azathioprine	C	Unknown	2-3 Mg/Kg	Not Reported
Ciclosporin	C	Unknown		Not Reported
Minocycline	C			Not Reported
Penicillamine	C	Unknown		Not Reported
Prednisone	C			Not Reported
Tocilizumab	C			Not Reported
Actemra	C			Not Reported
Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	15933671	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656078-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	16009048	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017285		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Plaquenil	S	Oral	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	16877937	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-28737		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported

Methotrexate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Unknown	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Simponi	S	Unknown	Unknown, Solution	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Piroxicam	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17411076	EXPEDITED (15-DAY)		HO	DE-SAMSUNG BIOEPIS-SB-2019-36506		83 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticular Perforation; Diverticulitis; Nausea; Vomiting	Benepali			S	Subcutaneous			Not Reported
	Hcq			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17574376	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001688			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Sarilumab			S	Subcutaneous	20 Mg, Qow		Not Reported
	Leflunomide			S	Oral	20 Mg		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Cyclosporin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Nicotinamide			S				Not Reported
	Folic Acid			S				Not Reported
	Esomeprazole Sodium			S				Not Reported
	Thiamine Hydrochloride			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown			Not Reported
	Nexium			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported

Ergocalciferol	C	Unk		Not Reported
Magnesium	C	Unk		Not Reported
Adalimumab	C			Not Reported
Xeljanz	C	Unk		Not Reported
Vitamin A	C			Not Reported
Vitamin C	C			Not Reported
Dexpanthenol	C			Not Reported
Nexium	C			Not Reported
Esomeprazole Magnesium Trihydrate	C			Not Reported
Riboflavin	C			Not Reported
Sodium Aurothiomalate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17774396	EXPEDITED (15-DAY)		OT	PHHY2019DE192157			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis Bacterial; Conjunctivitis Bacterial; Contusion; Cystitis; Diarrhoea; Fall; Myalgia; Osteoarthritis; Respiratory Tract Infection; Respiratory Tract Infection; Rhinitis; Sinusitis	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Abatacept			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17829520	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604568		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Nutropin			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported

Azathioprine	S		Not Reported
Calcium Carbonate	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Not Reported
Ciclosporin	S		Not Reported
Cyclophosphamide	S	Unknown	Not Reported
Enalapril	S	Unknown	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Metformin	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Methotrexate	S		Not Reported
Prednisone	S	Unknown	Not Reported
Somatrem	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Remicade	S		Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported
Acetazolamide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17851836	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605493		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Atenolol	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Co Atenolol	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Ferrous Fumarate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Palafer	S	Unknown	Not Reported
	Palafer Cf	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17931891	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012362			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Hydroxychloroquine			S	Unknown	Unk		Apotex

Osteoporosis	Methotrexate	S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk		Novartis
	Xeljanz	S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17995824	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200703535			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17998496	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004004988			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Electrocardiogram Qt Prolonged; Escherichia Bacteraemia; Hypothermia; Inflammation; Off Label Use; Overdose	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1200 Mg, Qd Film Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd,Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet		Concordia
	Paracetamol			C		Unk		Not Reported
	Tazocilline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18043432	EXPEDITED (15-DAY)		HO	NVSC2020US201598		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Infection	Gsk1120212			S	Oral	42 Mg, Unk		Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	13000 Mg		Not Reported
	Cephalexin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18077069	EXPEDITED (15-DAY)		OT	NVSC2020PT206822		79 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-	Azithromycin			S	Oral	500 Mg, Qd (500mg/Dia)		Novartis
	Plaquinol			S	Oral	400 Mg, Qd (400mg 12/12h Em D0)		Not Reported

Glutamyltransferase Increased; Hepatotoxicity	Acetylsalicylic Acid	C	Oral	150 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C	Oral	150 Mg, Qd (Ao Almoço)	Not Reported
	Levofloxacin	C	Intravenous (not otherwise specified)	750 Mg, 1 Total	Not Reported
	Ipratropium Bromide	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
	Haloperidol	C	Intramuscular	5 Mg, Prn	Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)	1000 Mg, Prn	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	4000 Mg, Qd	Not Reported
	Omeprazole	C	Oral	20 Mg, Qd	Not Reported
	Omeprazole	C	Oral	20 Mg, Qd	Not Reported
	Sodium Chloride	C	Intravenous (not otherwise specified)	500 Ml, Qd (2000 Ml Em D0)	Not Reported
	Salbutamol	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
	Quetiapine	C	Oral	50 Mg, Qd (Ao Pequeno-Almoço)	Not Reported
	Nebivolol	C	Oral	2.5 Mg, Qd (Ao Almoço)	Not Reported
	Rivastigmine	C	Transdermal	Unk	Not Reported
	Chlorpromazine	C	Unknown	Em Sos	Not Reported
	Memantine	C	Oral	20 Mg, Qd (Ao Pequeno-Almoço)	Not Reported
	Simvastatin	C	Oral	20 Mg, Qd (Ao Jantar)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18116197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2624769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18116347	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007576			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Major Depression	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18116584	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04176		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd (For 3 Days)		Lupin
	Mycophenolate Mofetil			C	Unknown	2000 Milligram, Qd		Not Reported
	Mycophenolate Mofetil			C	Unknown	1000 Milligram, Qd		Not Reported
	Mycophenolate Mofetil			C	Unknown	500 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	100 Milligram		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Dose Corresponding		Not Reported

To A Trough Goal Of 5-8 Microg/Ml.)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18116883	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1809847		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephropathy Toxic; Off Label Use; Renal Failure	Tacrolimus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Teva
	Hydroxychloroquine			S	Oral			Teva
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Mycophenolic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18116939	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04087		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrotising Retinitis	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Mycophenolate			S	Unknown	1000 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117162	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-04129		73 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117453	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201806-002129			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Fibrosis; Posterior Capsule Opacification	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod (Film Coated Tablet)		Concordia
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Methotrexate			C		Unk		Not Reported
	Foliamin			C		Unk		Not Reported
	Esomeprazole Magnesium			C		Unk		Not Reported
	Warfarin			C		Unk		Not Reported
	Minodronic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117490	EXPEDITED (15-DAY)		HO	CA-ACCORD-194289		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Myochrysine			S	Intramuscular	1 Every 2 Weeks, Solution Intramuscular		Not Reported
	Orencia			S	Unknown	1 Every 1 Weeks		Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Hydroxychloroquine		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Subcutaneous Solution	Not Reported
	Enbrel		S	Unknown	2 Every 1 Weeks	Not Reported
	Codeine		S	Unknown		Not Reported
	Ciclosporin		S	Unknown		Not Reported
	Alendronate Sodium/Alendronic Acid		S	Unknown		Not Reported
	Actemra		S	Unknown	1 Every 1 Months	Not Reported
	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Rituximab		S	Intravenous drip	2 Every 1 Days	Not Reported
	Actemra		S	Unknown	1 Every 4 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117689	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-219224			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Reaction	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117731	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Product Use	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Issue; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117754	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04178		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine Sulfate Tablets			S	Unknown	200 Milligram, Bid		Lupin
	Azithromycin Tablets			S	Unknown	500 Milligram, Qd		Lupin
	Lopinavir/Ritonavir			C	Unknown	2 Dosage Form, Bid		Not Reported
	Teriflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117761	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04090		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate Tablets			S	Unknown	1 Dosage Form, Bid		Lupin
	Lopinavir/Ritonavir			C	Unknown	200/50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117963	EXPEDITED (15-DAY)		OT	CA-ACCORD-194284			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117964	EXPEDITED (15-DAY)		OT	CA-ACCORD-194291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Retinopathy; Treatment Failure	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Plaquenil			S	Oral	1 Every 1 Days		Not Reported
	Myochrysine			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Demerol			C	Unknown			Not Reported
	Enbrel			C	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			C	Subcutaneous	1 Every 2 Weeks		Not Reported
	Morphine			C	Unknown			Not Reported
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported
	Tofacitinib			C	Oral	1 Every 12 Hours		Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported

Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Every 4 Weeks		Not Reported
Prednisone	C	Unknown	1 Every 1 Days		Not Reported
Prednisone	C	Unknown	1 Every 1 Days		Not Reported
Prednisone	C	Unknown	1 Every 1 Days		Not Reported
Prednisone	C	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117977	EXPEDITED (15-DAY)		OT	CA-ACCORD-194315			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S		1 Every 1 Weeks		Accord
	Hydroxychloroquine			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117981	EXPEDITED (15-DAY)		OT	CA-ACCORD-194318			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use,Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Unknown		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18117982	EXPEDITED (15-DAY)		OT	CA-ACCORD-194312		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response	Methotrexate			S				Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Etanercept			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S				Not Reported
	Leflunomide			S				Not Reported
	Naproxen			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Paracetamol			C				Not Reported
	Naproxen			C				Not Reported
	Diphenhydramine			C				Not Reported
	Iron			C				Not Reported
	Folic Acid			C				Not Reported
	Lasix			C				Not Reported
	Oxycontin			C				Not Reported

Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Oxyneo	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118065	EXPEDITED (15-DAY)		OT	NVSC2020US217087		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Metformin			C	Unknown	Unk		Not Reported
	Insulin Lispro			C	Unknown	Unk		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Apixaban			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118230	EXPEDITED (15-DAY)		OT	CA-ACCORD-194345		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Methotrexate			S	Subcutaneous			Accord
	Apo-Leflunomide			S	Unknown			Not Reported
	Certolizumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118303	EXPEDITED (15-DAY)		OT	CA-ACCORD-194302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular	1 Every 1 Weeks		Accord
	Naproxen			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Calcium Carbonate/Calcium Lactogluconate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C		Solution Subcutaneous		Not Reported
	Lozide			C				Not Reported
	Metformin			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported
	Colecalciferol			C				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118440	EXPEDITED (15-DAY)		OT	CA-ACCORD-194297			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Methotrexate		S	Subcutaneous		Accord
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gold		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Intravenous	Not Reported
	Methotrexate		S	Subcutaneous		Accord
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118449	EXPEDITED (15-DAY)		OT	CA-ACCORD-194292		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	1 Every 24 Hours		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 24 Hours		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			C	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118450	EXPEDITED (15-DAY)		OT	CA-ACCORD-194327			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Accord
	Orencia			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Prednisone			C				Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118452	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-194317			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Synovitis; Vomiting; Wheelchair User			otherwise specified)			
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone	S	Subcutaneous			Not Reported
	Triamcinolone	S	Unknown	Intra- Articular		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118781	EXPEDITED (15-DAY)		OT	CA-ACCORD-193870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Methotrexate			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	1 Every 1 Weeks, Not Specified, 1 Every 4 Weeks		Not Reported
	Arava			S	Oral	1 Every 1 Weeks		Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Certolizumab			S		1 Every 2 Weeks		Not Reported
	Ciclosporin			S	Oral	Not Specified		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, 1 Every 1 Weeks		Not Reported
	Enbrel			S		1 Every 1 Weeks		Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S				Not Reported

Infliximab	S	Intravenous (not otherwise specified)	Not Specified, 1 Every 1 Weeks		Not Reported
Lyrica	S				Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown	Not Specified		Not Reported
Prednisone	C				Not Reported
Piroxicam	C		Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118783	EXPEDITED (15-DAY)		HO	CA-ACCORD-194275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Etanercept			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous,1 Every 2 Weeks		Not Reported

Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119002	EXPEDITED (15-DAY)		OT	CA-ACCORD-194283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Methotrexate			S				Accord
	Ramipril			S		1 Every 1 Days		Accord
	Cyanocobalamin			S				Not Reported
	Arava			S				Not Reported
	Bisoprolol			S		1 Every 1 Days		Not Reported
	Buprenorphine			S		1 Every 1 Days		Not Reported
	Calcium Carbonate			S				Not Reported
	Fish Oil			S				Not Reported
	Furosemide/Potassium Chloride			S				Not Reported
	Lasix			S				Not Reported
	Magnesium Gluconate			S				Not Reported
	Plaquenil			S				Not Reported
	Pyridoxine			S				Not Reported
	Rivaroxaban			S		1 Every 1 Days		Not Reported
	Pyridoxine			S				Not Reported
	Ergocalciferol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119008	EXPEDITED (15-DAY)		OT	CA-ACCORD-193942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Mycophenolate Mofetil/Mycophenolate Sodium/Mycophenolic Acid			S		1 Every 1 Days		Not Reported
	Rosuvastatin			S				Not Reported

Ceftazidime/Ceftazidime Pentahydrate	S		Powder For Solution	Not Reported
Lasix	S			Not Reported
Piperacillin/Tazobactam	S			Not Reported
Plaquenil	S		1 Every 1 Days	Not Reported
Prednisone	S		1 Every 1 Days	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Vancomycin	S			Not Reported
Paracetamol	C			Not Reported
Amiodarone	C			Not Reported
Diphenhydramine	C			Not Reported
Eprex	C	Intravenous (not otherwise specified)		Not Reported
Escitalopram	C			Not Reported
Hydroxychloroquine	C			Not Reported
Hydrochlorothiazide	C			Not Reported
Insulin Lispro/Insulin Lispro Protamine Suspe	C			Not Reported
Januvia	C			Not Reported
Metformin	C			Not Reported
Metoprolol	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole	C			Not Reported
Piperacillin/Tazobactam	C			Not Reported
Potassium	C			Not Reported
Risedronate Sodium/Risedronic Acid	C			Not Reported
Risedronic Acid	C			Not Reported
Slow K	C			Not Reported
Tylenol	C			Not Reported
Ventolin	C			Not Reported
Methylprednisolone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119110	EXPEDITED (15-DAY)		OT	AU-ROCHE-2586225		5 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Morphoea; Off Label Use; Product Use In Unapproved Indication	Tocilizumab	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisolone	S	Oral	Not Reported
	Ruxolitinib	S	Oral	Not Reported
	Bosentan	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Betamethasone Dipropionate	C		Not Reported
	Cotrimoxazole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119162	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2020295960		56 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Plaquinol			S	Oral	400mg 12 / 12h In D0 And Then 200mg 12 / 12h		Not Reported
	Flucloxacillin			C	Intravenous (not otherwise specified)	12000 Mg, Daily		Not Reported
	Metamizole Magnesium			C	Intravenous (not otherwise specified)	2000 Mg, As Needed		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2000 Mg, Daily		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	1000 Ml, Daily		Not Reported
	Gentamicin			C	Intravenous (not	240 Mg, Daily		Not Reported

			otherwise specified)			
	Paracetamol	C	Oral	1000 Mg, As Needed		Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)	1000 Mg, As Needed		Not Reported
	Metamizole Magnesium	C	Oral	575 Mg, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119413	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous (Single Use Pre-Filled Syringe)		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown	Unknown		Not Reported
	Prednisone			C	Oral	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119439	EXPEDITED (15-DAY)		OT	BN-LUPIN PHARMACEUTICALS INC.-2020-04099		60 YR	Female	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block	Hydroxychloroquine			S	Unknown	400 Milligram, Stat Dose		Lupin

Right; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine	S	Unknown	200 Milligram, Bid (Dose Of 1,400 Mg)	Lupin
	Oseltamivir	S	Unknown	75 Milligram, Bid	Lupin
	Lopinavir/Ritonavir	S	Unknown	400 Mg/100 Mg, Bid	Not Reported
	Amoxicillin Clavulanic Acid	C	Intravenous (not otherwise specified)	1.2 Gram, Tid	Not Reported
	Meropenem	C	Unknown	1000 Milligram, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119775	EXPEDITED (15-DAY)		HO, OT	IR-IPCA LABORATORIES LIMITED-IPC-2020-IR-002527			Unknown	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Heart Injury; Myocarditis; Neonatal Respiratory Distress	Hydroxychloroquine			S	Transplacental	200 Milligram		Ipca
	Paracetamol Tablet			S	Transplacental	Unk		Not Reported
	Meropenem			S	Transplacental	1 Gram, Tid		Not Reported
	Vancomycin			S	Transplacental	1 Gram, Bid		Not Reported
	Tamiflu			S	Transplacental	75 Milligram, Bid		Not Reported
	Kaletra			S	Transplacental	400 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119905	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000147			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Unk		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qcy, Cimzia Single Use Pre-Filled		Not Reported

Arthritis; Stomatitis; Stomatitis; Therapeutic Product Effect Decreased; Weight Decreased				Syringe Dosage Form	
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Weekly	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Varenicline Tartrate	S	Oral	1 Dosage Form, Qd	Not Reported
	Valtrex	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Acetaminophen W/Oxycodone	C		Unk	Not Reported
	Esomeprazole Magnesium;Naproxen	C		Unk	Not Reported
	Rosuvastatin Calcium	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
	Naproxen	C		Unk	Not Reported
	Oxycodone Hydrochloride	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tofacltinlb Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119948	EXPEDITED (15-DAY)		CA, OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255813			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Block Congenital	Dexamethasone			S	Unknown	3.0 To 7.5 Mg/Day		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Immunoglobulin [Immunoglobulin Human Normal]			S	Unknown	20 G/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18119964	EXPEDITED (15-DAY)		CA, OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255815			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Block Congenital	Dexamethasone			S	Unknown	3 Milligram, Qd		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Immunoglobulin [Immunoglobulin Human Normal]			S	Unknown	20 Gram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18120104	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous, (Single Use Pre-Filled Syringe)		Not Reported
	Desoximetasone			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown	Unknown		Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Subcutaneous	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unknown		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18120324	NON-EXPEDITED			US-PFIZER INC-2020295118		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, 1x/Day		Not Reported
	Isoniazid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18120525	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1809048		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain	Methotrexate			S	Unknown			Barr
	Fentanyl			S	Unknown			Cephalon
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

In Extremity; Pleural Fibrosis; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased	Oxycontin	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18120714	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809622		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Hypersensitivity; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

Xeljanz	S	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog[Triamcinolone Acetonide]	C	Unknown	Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Orphenadrine Citrate	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18120840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809580		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported
	Cetirizine Hydrochloride	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Naproxen Sodium	C	Unknown	Not Reported
	Venlafaxine Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18120841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809667			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Off Label Use; Product Use Issue; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121051	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809180		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121080	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809195			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Methotrexate			S	Unknown	22.5 Mg		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121162	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1809399		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma;	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Hydroxychloroquine Sulfate	S	Oral	200 Milligram Daily;	Not Reported
	Isoniazid	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121163	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809245		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown	15 Mg		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121174	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809456		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate		S	Unknown	20 Mg, 1 Every 1 Week	Barr
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported
	Advil [Ibuprofen]		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Ketorolac		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121178	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809615		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported

	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Arthrotec	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121180	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809611		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown	40 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan			C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan			C	Unknown	50 Microgram Daily;		Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121183	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809626		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Methotrexate	S	Unknown	25 Mg, 1 Every 1 Week	Barr
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122160	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-037414		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Small For Dates Baby; Systemic Lupus Erythematosus	Carvedilol			S	Unknown	Unk		Aurobindo
	Ramipril			S	Unknown	Unk		Aurobindo
	Ethinylestradiol/Norethisterone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S	Oral	50 Milligram, 3 Times A Day		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Epratuzumab		S	Unknown	Unk	Not Reported
	Atorvastatin		S	Unknown	Unk	Not Reported
	Aspirin		S	Oral	81 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	13136342	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1644573-00		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Piroxicam			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	13162671	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1777383-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Celebrex			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	13188059	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2017GMK026159			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Gabapentin			S	Unknown	100 Mg, Bid		Glenmark
	Gabapentin			S	Unknown	100 Milligram, Unk		Glenmark
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qw	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl Citrate	S	Epidural	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Od	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Od	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Apo Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported

Methotrexate	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Od	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Od	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Od, 1 Every 1 Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Od, 1 Every 1 Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg, Od	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Od	Not Reported
Leflunomide	S	Oral	20 Mg, Od (1 Every 1 Day)	Not Reported
Apo Gabapentin	S	Oral	100 Mg, Bid (2 Every 1 Day)	Not Reported
Apo Gabapentin	S	Unknown	Unk	Not Reported
Apo Celecoxib	S	Oral	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
Nortriptyline Hydrochloride	S	Oral	10 Milligram, 1 Every 1 Hour	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Once Every 3 Weeks (Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	Unk(Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	Unk(Solution Intramuscular); Once Every 3 Weeks	Not Reported
Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Orencia	S	Intravenous (not	750 Mg, 1 Every 1 Month	Not Reported

		otherwise specified)		
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Weeks	Not Reported
Orencia	S	Subcutaneous	Unk, Qw, 1 Every 1 Week	Not Reported
Orencia	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Week	Not Reported
Orencia	S	Vaginal	750 Milligram, 1 Every 1 Month	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Od	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od, 1 Every 1 Day	Not Reported
Sulfasalazine	S	Oral	2.5 Gram, Od	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	468 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk, Od	Not Reported
Calcium	C	Unknown	Unk, Od	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Od	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Cyclical	Not Reported
Trazodone Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, 1 Every 1	Not Reported

			Hour	
Trazodone Hydrochloride	C	Oral	50 Mg, Od	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Od	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Od	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1 Every 1 Hour	Not Reported
Ergocalciferol	C	Unknown	400 Dosage Form, Od	Not Reported
Ergocalciferol	C	Unknown	1 Dosage Form, Od	Not Reported
Esomeprazole /01479302/	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole /01479302/	C	Unknown	400 Milligram, Bid	Not Reported
Esomeprazole /01479302/	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Od	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	10 Milligram, Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Od	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Unknown	10 Milligram, Od	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Od	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Od	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	2.5 Milligram	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid	Not Reported

Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Od	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Milligram, Od	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Omega 3 /01333901/	C	Unknown	1200 Mg, Bid	Not Reported
Omega 3 /01333901/	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Dosage Form, Prn	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Dosage Form, Unk	Not Reported
Actonel	C	Unknown	36 Mg, Qw	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk, Od	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks (Intravenous Solution)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk (1 Every 2 Weeks)	Not Reported
Vitamin D /00107901/	C	Unknown	400 Df, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	Unk	Not Reported

Vitamin D /00107901/	C	Unknown	400 International Unit, Qd	Not Reported
Tylenol /00020001/	C	Oral	1000 Milligram, Od	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Oral	1000 Milligram, Od	Not Reported
Multivitamin /00097801/	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	40 Mg, Qd	Not Reported
Tecta	C	Unknown	40 Mg, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Biotin W/Calcium Pantothenate/Colec/06004901/	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid	C	Unknown	1 Df, Qd (1 Every 1 Day)	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk, Cyclical	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk, Od	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nexium /01479302/	C	Unknown	40 Milligram, Bid	Not Reported

Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclical	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk, Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Gigabecquerel, 1 Evrey 1 Hour	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk, Od, 1 Every 1 Day	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	400 Milligram, Od	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Od	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Perfenazine	C	Oral	10 Milligram, Unk	Not Reported
Perfenazine	C	Unknown	40 Mg, Od, 1 Every 1 Day	Not Reported
Perfenazine	C	Oral	10 Milligram, Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported

Fergon	C	Unknown	300 Milligram, Od	Not Reported
Fergon	C	Unknown	300 Milligram, Od	Not Reported
Fergon	C	Unknown	Unk	Not Reported
Percocet /00867901/	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Vitamin E /00110501/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Omega-3 /01866101/	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	10 Milligram, Cyclical	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	2.5 Milligram, Od	Not Reported
Actonel	C	Unknown	36 Milligram, Qw	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Od	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Diphenoxylate	C	Unknown	2.5 Milligram, Od	Not Reported
Diphenoxylate	C	Unknown	1 Dosage Form, Od	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Ophthalmic	Unk	Not Reported
Oxycodone Hydrochloride W/Oxycodone Terephtha	C	Unknown	1 Df, Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported

Vitamin B12 Aaa	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Unknown	480 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Unknown	488 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Unk	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	2.5 Milligram, Unk	Not Reported
Lomotil /00034001/	C	Unknown	2.5 Milligram, Od	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qw	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qw	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulf	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	1 Dosage Form	Not Reported
Acetaminophen	C	Oral	1000 Milligram, Od	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Esomeprazole /01479302/	C	Oral	400 Milligram, Bid	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Od	Not Reported
Loperamide	C	Unknown	2.5 Milligram, Unk	Not Reported
Omega-3 /01866101/	C	Unknown	1200 Milligram, Bid	Not Reported
Xeljanz	C	Oral	5 Milligram, Od	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

Xeljanz	C	Oral	5 Milligram, Od		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk		Not Reported
Atropine Sulfate W/Diphenoxylate Hydrochlor.	C	Unknown	Unk		Not Reported
Cyanocobalamin	C	Unknown	Unk		Not Reported
Fish Oil W/Tocopherol	C	Unknown	1200 Milligram, Bid		Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Bid		Not Reported
Vitamin B1 /00056101/	C	Unknown	Unk		Not Reported
Oxycodone Terephthalate	C	Unknown	Unk		Not Reported
Epa Dha 720	C	Unknown	Unk		Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid		Not Reported
Nasonex	C	Unknown	2 Dosage Form, Bid		Not Reported
Nasonex	C	Unknown	Unk		Not Reported
Percocet /00867901/	C	Unknown	1 Dosage Form, Prn		Not Reported
Thiamine	C	Unknown	Unk		Not Reported
Vitamin B6	C	Unknown	Unk		Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	13564686	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1975999-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	14878384	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2346040-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	15627288	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557075-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arthrotec			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Mefenamic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	15663251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570496-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
					Hydroxychloroquine	S	Unknown			Not Reported
					Sulfasalazine	S	Unknown			Not Reported
					Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	15707043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S	Unknown	Unk		Amgen
	Otezla			S	Oral	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	16723453	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557368-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Discomfort; Drug Ineffective; Erythema; Joint Swelling; Lower Respiratory Tract Infection; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	16911065	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2906371-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Crohn'S Disease; Drug Ineffective; Dysphonia; Frequent Bowel Movements; Fungal Infection; Haemorrhage; Palpitations; Pharyngeal Disorder; Pneumothorax; Pulmonary Embolism; Skin Ulcer; Speech Disorder; Stress	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17084153	EXPEDITED (15-DAY)		OT	NVSC2019TW043890			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Auditory Disorder; Congenital Anomaly; Foetal Exposure During Pregnancy; Foetal Malformation; Hypertelorism Of Orbit; Micrognathia; Microtia	Mycophenolate Mofetil		S	Transplacental	1000 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate		S	Transplacental	200 Mg, Qd	Novartis
	Irbesartan		S	Transplacental	150 Mg, Qd	Not Reported
	Prednisolone		S	Transplacental	30 Mg, Qd	Not Reported
	Felodipine		S	Transplacental	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17188271	EXPEDITED (15-DAY)		OT	NVSC2019CA075047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17225487	EXPEDITED (15-DAY)		OT	NVSC2019CA083831		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk, (Solution)		Not Reported
	Actemra			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk, (Via Int Corp Caver And Via Oral)		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Oral	Unk		Not Reported

	Plaquenil	S	Oral	1 Df, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Oral	1 Df, Qd, 1 Dosage Form, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17227197	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0002		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Prevnar 13			S	Intramuscular	Single Dose		Not Reported
	Depo-Medrol With Lidocaine			S	Intra-articular			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine Sodium			S	Oral			Not Reported
	Azathioprine Sodium			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	2x/Week		Not Reported
	Ketoprofen			S	Topical			Not Reported
	Leucovorin Calcium			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Subcutaneous	Not Reported
Plaquenil	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Imuran	S	Oral	Not Reported
Methotrexate Sodium	C	Unknown	Not Reported
Lederle Leucovorin	C	Unknown	Not Reported
Shingrix	C	Unknown	Not Reported
Corticosteroids	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17278312	EXPEDITED (15-DAY)		OT	NVSC2019CA086423		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Cetrizine			S	Unknown	10 Mg		Not Reported
	Cetrizine			S	Unknown	25 Mg		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S			Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Hydrocortisone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Sulfasalazine	S	Subcutaneous	1 G, Qd	Not Reported

	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Topicort	S	Subcutaneous	Unk	Not Reported
	Topicort	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17609185	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANZ PHARMA-GSH201702-001124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	5 Mg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	5 Mg		Concordia
	Hydroxychloroquine			S				Concordia
	Adalimumab			S	Unknown	Unknown		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)	250 Mg, Monthly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Weekly		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Etanercept			S	Subcutaneous	12.5 Mg, Weekly		Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]			S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported

Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Unevaluable Event; Vomiting; Vomiting; Wheelchair User	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Methotrexate	S	Unknown	Unk, Weekly	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Enbrel	S	Unknown	12.5 Unk	Not Reported
	Tocilizumab	S	Unknown	250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg Qcy (Every 2 Week)	Not Reported
	Isoniazid;Rifampicin	S	Intravenous (not	Unknown	Not Reported

			otherwise specified)		
	Humira	S	Subcutaneous	Unk	Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Triamcinolone Hexacetonide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17644416	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002706			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Acute Respiratory Distress Syndrome; Off Label Use; Pulmonary Embolism; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Morphine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17650023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145382		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis; Sleep Disorder	Etanercept			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Endocervical	Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Pfizer
	Actemra			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
Myochrysine	S	Intramuscular	Unk		Not Reported
Otezla	S	Oral	Unk		Not Reported
Sirukumab	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Ustekinumab	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17688557	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202003002806			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Off Label Use; Organ Failure; Septic Shock	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia
	Rocephine			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Suxamethonium			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Sulfentanyl			C		Unk		Not Reported
	Carteol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17692715	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004002846			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use; Pneumonia Bacterial; Pneumonia Bacterial; Staphylococcal Bacteraemia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600 Mg, Qd, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd		Concordia
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported
	Spiramycin			S		6 Mu, Qd		Not Reported
	Vancomycine			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Vancomycine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17835075	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2020204780		73 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Electrocardiogram Qt Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Once A Day		Pfizer
	Reuquinol			S		400 Mg, Every 12 Hours Before Sleep		Not Reported
	Reuquinol			S	Oral	400 Mg, Once A Day		Not Reported
	Oseltamivir			C		75 Mg, 2x/Day		Not Reported
	Oseltamivir			C		75 Mg, 1x/Day		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 4x/Day Every 6 Hours		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 3x/Day Every 8 Hours		Not Reported
	Sodium Bicarbonate			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day Every 8 Hours		Not Reported

Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisonal [Hydrocortisone]	C	Intravenous (not otherwise specified)	100 Mg, 2x/Day Every 12 Hours	Not Reported
Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Encrise	C	Intravenous (not otherwise specified)	20 Iu, As Needed	Not Reported
Fentanest [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	2500 Ug, As Needed	Not Reported
Norepinephrine Bitartrate	C	Intravenous (not otherwise specified)	32 Mg, As Needed	Not Reported
Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
Hepamax S	C		Unk	Not Reported
Novalgina	C	Intravenous (not otherwise specified)	1 G, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17845972	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1241448		88 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Hypertransaminasaemia; Off Label Use	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17859197	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1243302		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Face Oedema; Localised Oedema; Off Label Use; Skin Exfoliation	Darunavir		S	Oral	800 Mg	Teva
	Ritonavir Sandoz		S	Oral	1 Dosage Forms	Not Reported
	Plaquenil		S	Oral	2 Dosage Forms	Not Reported
	Tazocin 4 G/0,5 G Polvere Per Soluzione Per Infusione		S		4 Gram	Not Reported
	Clexane		S	Subcutaneous	1 Dosage Forms	Not Reported
	Depakin Chrono 300 Mg Compresse A Rilascio Prolungato		C			Not Reported
	Insulin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17892461	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-028600		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Levofloxacin			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17927475	EXPEDITED (15-DAY)		HO, OT	NVSC2020FR172934		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pneumonia Bacterial; Pneumonia Bacterial; Pneumonia Klebsiella; Staphylococcal Bacteraemia; Staphylococcal Infection	Vancomycin			S	Intravenous (not otherwise specified)	2 G, Qd		Novartis
	Vancomycin			S				Novartis
	Spiramycin			S	Other	6 Df, Qd (6 Mu, Qd)		Not Reported
	Hydroxychloroquine Sulphate			S	Other	600 Mg, Qd		Not Reported
	Hydroxychloroquine Sulphate			S	Other	400 Mg, Qd (Last Dose Was Received On 08 Apr 2020)		Not Reported
	Cefotaxime Sodium			S	Intravenous (not	6 G, Qd		Not Reported

	Cefotaxime Sodium		S	otherwise specified) Intravenous (not otherwise specified)	6 G, Qd (Last Dose Was Received On 09 Apr 2020)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17933068	EXPEDITED (15-DAY)		OT	CA-ROCHE-2626024		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17993125	EXPEDITED (15-DAY)		OT	NVSC2020US189068			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk (Maternal Dose: Unknown)		Novartis
	Dexamethasone			S	Transplacental	Unk (Maternal Dose: 4mg Qd Tapered To 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18001421	EXPEDITED (15-DAY)		CA	NVSC2020ES191925			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ductus Arteriosus Premature Closure; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18036988	EXPEDITED (15-DAY)		HO	CA-ACCORD-190371			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	4 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Infliximab			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Enbrel			S	Subcutaneous	4 Every 1 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported

Prednisone	S	Oral	2 Every 1 Days		Not Reported
Triamcinolone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18077218	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2020281722		54 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Plaquinol			S	Oral	400 Mg, 1x/Day (400 Mg Every 12h On Day0, Then 200 Mg Every 12h)		Not Reported
	Calcium Polystyrene Sulfonate			C		2 G, 1x/Day		Not Reported
	Abacavir/Dolutegravir/Lamivudine			C	Oral	1 Df, 1x/Day		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2000 Mg, 1x/Day		Not Reported
	Bisacodyl			C	Oral	5 Mg, 1x/Day		Not Reported
	Potassium Dihydrogen Phosphate			C	Intravenous (not otherwise specified)	10 Meq, 1x/Day		Not Reported
	Paracetamol			C	Oral	1000 Mg, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18083066	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202007007376			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Proctectomy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Bid, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd, Film-Coated Tablet		Concordia

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18083694	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2020-036488		79 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Covid-19 Treatment; Gamma-Glutamyltransferase Increased; Hepatotoxicity	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquinol			S	Oral	400 Milligram, Once A Day(400mg 12/12h Em D0)		Not Reported
	Haloperidol-Ratiopharm			C	Intramuscular	5 Milligram		Not Reported
	Levofloxacin			C	Intravenous (not otherwise specified)	750 Milligram, 1 Total		Not Reported
	Omeprazole			C	Oral	20 Milligram, Once A Day		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetylsalicylic Acid			C	Oral	150 Milligram, Once A Day		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	500 Milliliter, Once A Day(2000 Ml Em D0)		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	4000 Milligram, Once A Day		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	2 Dosage Form, Once A Day		Not Reported
	Salbutamol			C	Respiratory (inhalation)	2 Dosage Form, Once A Day		Not Reported
	Quetiapine			C	Oral	50 Milligram, Once A Day (Ao Pequeno-Almoço At Breakfast)		Not Reported
	Nebivolol Aurobindo			C	Oral	2.5 Milligram, Once A Day (Ao Almoço At Lunch)		Not Reported
	Rivastigmine			C	Transdermal	Unk		Not Reported
	Chlorpromazine			C	Unknown	Unk (Em Sos In Sos)		Not Reported
	Memantine			C	Oral	20 Milligram, Once A Day (Ao Pequeno-Almoço At Breakfast)		Not Reported

	Simvastatin	C	Oral	20 Milligram, Once A Day (Ao Jantar At Dinner)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18090572	EXPEDITED (15-DAY)		OT	CA-ACCORD-192214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Oral			Accord
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Not Specified		Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Dosage Form:Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Not Specified		Not Reported
	Prednisone			S	Oral			Not Reported
	Pseudoephedrine			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Methotrexate	S	Intra-arterial	Accord
	Methotrexate	S	Unknown	Accord
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18105469	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2020-037663		86 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Nausea	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram (1 Total)		Not Reported
	Plaquinol			S	Oral	Unk (400mg 12 / 12h In D0 And Then 200mg 12 / 12h)		Not Reported
	Piperacilina + Tazobactam			C	Intravenous (not otherwise specified)	18000 Milligram, Once A Day		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	Unk, Sos (As Necessary)		Not Reported
	Furosemide			C	Oral	40 Milligram, Once A Day		Not Reported
	Gabapentin			C	Oral	200 Milligram, Once A Day		Not Reported
	Enoxaparin Sodium			C	Unknown	40 Milligram, Once A Day		Not Reported
	Escitalopram			C	Oral	10 Milligram, Once A Day		Not Reported
	Amlodipine			C	Oral	5 Milligram, Once A Day		Not Reported
	Metoclopramide			C	Intravenous (not	Unk (Sos Up To A		Not Reported

			otherwise specified)	Maximum Of 30 Mg / Day) As Necessary	
	Pantoprazole	C	Oral	20 Milligram, Once A Day	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Milligram, Once A Day	Not Reported
	Acetylsalicylic Acid	C	Oral	100 Milligram, Once A Day	Not Reported
	Potassium Chloride	C	Intravenous (not otherwise specified)	40 Milliequivalent, Two Times A Day	Not Reported
	Potassium Chloride	C	Oral	1200 Milligram, Once A Day	Not Reported
	Bromazepam	C	Oral	Unk,Sos Up To 1.5 Mg / Day As Necessary	Not Reported
	Losartan + Hidroclorotiazida	C	Oral	1 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18109256	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202007007450			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Corynebacterium Infection; Cough; Covid-19; Enterococcal Infection; Fluid Overload; Hyperkalaemia; Leukocytosis; Morganella Infection; Off Label Use; Pleural Effusion; Pneumonia; Pneumonia Klebsiella; Polyomavirus Viraemia; Pulmonary Oedema; Pyrexia; Renal Tubular Necrosis; Respiratory Distress; Respiratory Failure; Staphylococcal Bacteraemia;	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Azithromycin 250 Mg			S	Unknown	250 Mg, Qd		Not Reported
	Mycophenolic Acid			S	Unknown	200 Mg, Qd		Not Reported
	Mycophenolic Acid			S	Unknown	100 Mg, Qd		Not Reported
	Mycophenolic Acid			S	Unknown	500 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Adriamycin Hydrochloride			C				Not Reported

Staphylococcal Infection; Stenotrophomonas Infection; Urinoma; Wound Infection Bacterial

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18120981	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	1800 Milligram Daily;		Not Reported
	Premarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121079	NON-EXPEDITED			US-ADVANZ PHARMA-202007007551			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz Xr			C	Oral	11 Mg, Once A Day, Taking Xeljanz For 3-4		Not Reported

Years

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121093	EXPEDITED (15-DAY)		HO	CA-ACCORD-194265		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Atenolol/Atenolol Hydrochloride			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Methotrexate			S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121095	EXPEDITED (15-DAY)		HO	CA-ACCORD-194269			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Not Specified		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Hydroxychloroquine		S	Oral		Not Reported
	Immunoglobulin Human Normal		S	Intravenous (not otherwise specified)		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Specified	Not Reported
	Sulfasalazine		S	Oral	Not Specified	Not Reported
	Triamcinolone		S	Unknown	Dosage Form: Suspension Intraarticular	Not Reported
	Apo-Prednisone		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121196	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809246		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121200	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809192		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Subcutaneous			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121202	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809190		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121204	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1809075			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use;	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18121238	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Meloxicam	C			Not Reported
Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122070	EXPEDITED (15-DAY)		OT	CA-ACCORD-194463			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Certolizumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown	Tofacitinib Citrate		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122077	EXPEDITED (15-DAY)		HO, OT	GR-ACCORD-194206		60 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Drug Hypersensitivity; Eosinophilia; Erythema Multiforme; Fatigue; Rash Erythematous; Rash Pruritic; Skin Plaque	Hydroxychloroquine			S		200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122110	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809395		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown			Teva
	Risedronate Sodium			S	Oral			Teva
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122189	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122201	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810536		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122240	EXPEDITED (15-DAY)		OT	CA-ACCORD-194454		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Intravenous	Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Arthrotec		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Azathioprine		C	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122241	EXPEDITED (15-DAY)		HO	CA-ACCORD-194452			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Orencia		S	otherwise specified) Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Intra-articular	Intra-Articular	Not Reported
	Apo-Prednisone		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122242	EXPEDITED (15-DAY)		HO	CA-ACCORD-194451		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia;	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Nortriptyline			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Paracetamol	C	Unknown	Not Reported
	Aclasta	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Fentanyl	C	Unknown	Not Reported
	Iron	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Oxycodone	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Nicotinamide	C	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122243	EXPEDITED (15-DAY)		OT	CA-ACCORD-194456		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122244	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-194457			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122245	EXPEDITED (15-DAY)		OT	CA-ACCORD-194460		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	1 Every 1 Days		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122248	EXPEDITED (15-DAY)		OT	CA-ACCORD-194323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Grip Strength Decreased; Hepatitis; Pain	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Indometacin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122262	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809362			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122373	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809244		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	Neurontin			C	Unknown	1800 Milligram Daily;		Not Reported
	Premarin			C				Not Reported
	Tylenol			C	Unknown	1300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122376	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809175		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122386	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255739		75 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122409	EXPEDITED (15-DAY)		HO, OT	NL-ADVANZ PHARMA-GSH201609-004748			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haemolytic Anaemia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	1 Dosage Form, Qd	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	Unk	Concordia
	Etanercept		S	Subcutaneous	1 Dosage Form, Weekly	Not Reported
	Sulfasalazine		S	Oral	2 Dosage Form, Unk, (Frequency: 2dd 4)	Not Reported
	Methotrexate		S	Oral	1 Dosage Form, Weekly	Not Reported
	Lisinopril		C		Unk	Not Reported
	Bisoprolol		C		Unk	Not Reported
	Pantozol		C		Unk	Not Reported
	Dyazide		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122460	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24106		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Therapeutic Product Effect Decreased; Ulcer	Etanercept			S	Unknown	Unknown		Not Reported
	Celebrex			S	Oral			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Betaloc [Metoprolol Tartrate]			C	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Losec [Omeprazole]			C	Unknown	Unknown		Not Reported
	Synthroid			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122461	EXPEDITED (15-DAY)		HO, OT	PL-SAMSUNG BIOEPIS-SB-2020-24478		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn	Benepali			S	Unknown	Unknown		Not Reported
	Encorton			S	Unknown			Not Reported
	Encorton			S	Unknown			Not Reported
	Erelzi			S	Subcutaneous			Not Reported
	Erelzi			S	Subcutaneous			Not Reported
	Erelzi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Folic			C	Unknown	Unknown		Not Reported
	Insulin			C	Unknown	Unknown		Not Reported
	Metex			C	Subcutaneous	Unknown		Not Reported
	Metex			C	Subcutaneous	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122525	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810480			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122528	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122594	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810281		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122709	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-MAPI_00010766			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid		Concordia
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported

	Kineret	S	Unknown	Unk		Not Reported
	Meloxicam	C		Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122748	EXPEDITED (15-DAY)		OT	CA-ACCORD-194516			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S	Intratumor			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Infliximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122776	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2020-04287		50 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122893	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1069912		56 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Mylan
	Plaquinol			S	Oral	400 Milligram, Qd, 400mg 12 / 12h In D0 And Then 200mg 12 / 12h		Mylan

	Flucloxacillin	C	Intravenous (not otherwise specified)	12000 Milligram, Qd	Mylan
	Metamizole Magnesium	C	Intravenous (not otherwise specified)	2000 Milligram, As Necessary	Mylan
	Ceftriaxone	C	Intravenous (not otherwise specified)	2000 Milligram, Qd	Mylan
	Sodium Chloride	C	Intravenous (not otherwise specified)	1000 Milliliter, Qd	Mylan
	Gentamicin	C	Intravenous (not otherwise specified)	240 Milligram, Qd	Mylan
	Paracetamol	C	Oral	1000 Milligram, As Necessary	Mylan
	Metamizole Magnesium	C	Oral	575 Milligram, As Necessary	Mylan
	Paracetamol	C	Intravenous (not otherwise specified)	1000 Milligram, As Necessary	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122913	EXPEDITED (15-DAY)		OT	CA-ACCORD-193842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Unknown	Not Specified		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122915	EXPEDITED (15-DAY)		OT	CA-ACCORD-194410			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S				Accord
	Actemra			S		Frequency: 1 Every 1 Weeks		Not Reported
	Apo-Azathioprine			S				Not Reported
	Arava			S				Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Frequency: 1 Every 1 Weeks Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous, Frequency: 1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122916	EXPEDITED (15-DAY)		OT	CA-ACCORD-193843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolic Acid			S	Unknown			Accord
	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Lyrica	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Intravenous		Not Reported
Rituximab	S	Unknown			Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Piroxicam	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18122921	EXPEDITED (15-DAY)		HO	CA-ACCORD-194571		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Gabapentin			S	Oral	2 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Atropine Sulfate/Diphenoxylate Hydrochloride			C				Not Reported
	Esomeprazole/Esomeprazole			C				Not Reported

	Magnesium/Esomeprazole Sodium		
	Ferrous Gluconate	C	Not Reported
	Aclasta	C	Not Reported
	Loperamide	C	Not Reported
	Ergocalciferol	C	Not Reported
	Acetaminophen	C	Not Reported
	Nasonex	C	Not Reported
	Oxycodone	C	Not Reported
	Pantoprazole	C	Not Reported
	Prednisone	C	Not Reported
	Risedronic Acid	C	Not Reported
	Trazodone	C	Not Reported
	Tylenol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123059	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809092			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral	1000 Milligram Daily;		Not Reported
	Naprosyn [Naproxen]			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123074	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1809500		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

						otherwise specified)				
				Rituximab	S	Unknown				Not Reported
				Sodium Aurothiomalate	S	Unknown				Not Reported
				Sodium Aurothiomalate	S	Unknown				Not Reported
				Sulfasalazine	S	Unknown				Not Reported
				Sulfasalazine	S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123100	EXPEDITED (15-DAY)		DE, LT	CA-ACCORD-194472			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123110	EXPEDITED (15-DAY)		OT	CA-ACCORD-194464			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution, 1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Subcutaneous Solution, 1 Every 1 Weeks		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123112	EXPEDITED (15-DAY)		OT	CA-ACCORD-194471			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	S	Unknown			Not Reported
Loperamide	C	Oral			Not Reported
Xeljanz	C	Oral	2 Every 1 Days		Not Reported
Pantoprazole	C	Unknown	3 Every 1 Days		Not Reported
Bifidobacterium Bifidum	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123150	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810177		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123198	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3476689-00		53 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 200/50			S	Oral	Lopinavir: 200mg; Ritonavir: 50mg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Ondansetron			S	Intravenous (not			Not Reported

			otherwise specified)		
	Haloperidol	S	Intramuscular		Not Reported
	Haloperidol	S	Intramuscular		Not Reported
	Amoxicillin/Clavulanic Acid	C	Intravenous (not otherwise specified)	Every 6 Hours	Not Reported
	Midazolam	C			Not Reported
	Enoxaparin	C			Not Reported
	Paracetamol	C			Not Reported
	Paracetamol	C		Dose Decreased As Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123262	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810407		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123279	EXPEDITED (15-DAY)		OT	CA-ACCORD-194448		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Oral	1 Every 24 Hours		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 24 Hours		Not Reported

	Lyrica	S	Oral	2 Every 1 Days		Not Reported
	Tylenol	C				Not Reported
	Xeljanz	C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123280	EXPEDITED (15-DAY)		OT	CA-ACCORD-194449		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Methotrexate			S	Oral			Accord
	Apo-Leflunomide			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S				Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Methotrexate			S	Subcutaneous			Accord
	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported

	Neoral	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123282	EXPEDITED (15-DAY)		OT	CA-ACCORD-194534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Cortisone			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123283	EXPEDITED (15-DAY)		OT	CA-ACCORD-194446		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology	Methotrexate			S		1 Every 1 Weeks		Accord

Abnormal; Drug Ineffective; Drug Intolerance; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra	S			Not Reported
	Arava	S	Oral	1 Every 1 Days	Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous	Not Reported
	Enbrel	S			Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	1 Every 12 Hours	Not Reported
	Leflunomide	S		1 Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Every 1 Days	Not Reported
	Sulfasalazine	S		1 Every 1 Days	Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C		1 Every 1 Days	Not Reported
	Xeljanz	C	Oral	1 Every 12 Hours	Not Reported
	Hydroxychloroquine	S		1 Every 12 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123287	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810464		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123292	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Acetaminophen And Codeine	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123294	EXPEDITED (15-DAY)		OT	CA-ACCORD-194298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Methotrexate			S	Unknown			Accord
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Codeine/Paracetamol			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Methotrexate	S	Unknown	Accord
	Actemra	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123295	EXPEDITED (15-DAY)		HO	CA-ACCORD-194299		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Apo-Gabapentin			S	Oral	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular	Dosage Form: Solution Intramuscular		Not Reported
	Oxycodone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Not Specified		Not Reported
	Oxycodone Hydrochloride/Paracetamol			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Biotin			C		Not Specified		Not Reported
	Diphenoxylate			C				Not Reported
	Esomeprazole			C	Unknown	Not Specified		Not Reported
	Iron			C		Not Specified		Not Reported

Loperamide	C	Unknown			Not Reported
Nortriptyline	C	Unknown			Not Reported
Oxycodone	C		Not Specified		Not Reported
Pantoprazole	C				Not Reported
Perphenazine	C		Not Specified		Not Reported
Prednisone	C		Not Specified		Not Reported
Pyridoxine	C	Unknown	Not Specified		Not Reported
Retinol	C	Unknown	Not Specified		Not Reported
Riboflavin	C		Not Specified		Not Reported
Risedronic Acid	C	Unknown	Not Specified		Not Reported
Thiamine	C		Not Specified		Not Reported
Thiamine	C				Not Reported
Trazodone	C				Not Reported
Tylenol	C	Unknown	Not Specified		Not Reported
Retinol	C	Unknown			Not Reported
Ascorbic Acid	C	Unknown			Not Reported
Colecalciferol	C				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123493	EXPEDITED (15-DAY)		HO	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-061652			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diabetic Eye Disease; Rheumatoid Arthritis	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Monthly		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123851	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04355		65 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Darunavir			C	Unknown	800 Milligram, Qd		Not Reported
	Cobicistat			C	Unknown	150 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123915	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810231		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123916	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810384		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123917	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1810266			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported

Ilaris Single-Use Vial	S			Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S			Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123994	EXPEDITED (15-DAY)		HO	CA-SCIEGEN-2020SCILIT00174		11 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence; Respiratory Depression	Gabapentin Tablets			S	Oral			Sciegen
	Aripiprazole			S	Oral			Sciegen
	Fluoxetine Tablets,Usp 20 Mg.			S	Oral			Sciegen
	Ascorbic Acid			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Bisacodyl			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Clobazam			S	Oral			Not Reported
	Clonidine			S	Oral	0.05mg Every Morning And 0.1mg Every Evening		Not Reported
	Colecalciferol			S	Unknown	2000 Units		Not Reported
	Dimenhydrinate			S	Oral			Not Reported
	Diphenhydramine			S	Oral	Every 6 Hours As Required		Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid/Omega-3-Fatty Acid			S	Oral	200/400/1000 Mg		Not Reported
	Fluticasone			S	Respiratory	2 Puffs Daily (250microg		Not Reported

			(inhalation)	Per Actuation)	
	Hydroxychloroquine	S	Oral		Not Reported
	Hydromorphone	S	Unknown	Immediate Release	Not Reported
	Ketorolac	S	Oral	Every 6 Hours	Not Reported
	Leuprorelin	S	Intramuscular	Every 30 Days	Not Reported
	Lorazepam	S	Sublingual	0.5 Mg And 2 Mg As Required	Not Reported
	Melatonin	S	Oral	Every Night	Not Reported
	Methadone	S	Oral		Not Reported
	Methocarbamol/Paracetamol	S	Oral	400/500 Mg	Not Reported
	Montelukast	S	Oral		Not Reported
	Pantoprazole	S	Oral		Not Reported
	Phenobarbital	S	Oral		Not Reported
	Polyethylene Glycol	S	Oral		Not Reported
	Ranitidine	S	Oral		Not Reported
	Salbutamol Sulfate	S	Respiratory (inhalation)	2 Puffs Every 4 Hours As Required (100 Microg Per Actuation)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810542			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124077	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810440		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Methotrexate			S	Subcutaneous	25 Milligram Daily;		Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	7 Milligram Daily;		Not Reported
	Apo-Ramipril			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Acetaminophen/Caffeine/Dihydrocodeine Bitartrate			C	Unknown			Not Reported
	Acetaminophen/Codeine			C	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			C	Ophthalmic			Not Reported
	Hydroxychloroquine Sulfate			C	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124111	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling;	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported

Rheumatoid Arthritis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124117	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810305			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Retinopathy; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Codeine			C	Unknown			Not Reported
	Demerol			C	Unknown			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Morphine			C	Unknown			Not Reported
	Prednisone			C	Unknown	2 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	3 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	4 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	1 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124135	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810467		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Methotrexate		S	Unknown	25 Milligram Daily;	Barr
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124136	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1810248			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124183	EXPEDITED (15-DAY)		DE, HO	BE-MYLANLABS-2020M1069820		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Symptom Masked	Enoxaparin			S	Subcutaneous	40 Milligram, Qd, Later Dose Increased		Mylan
	Enoxaparin			S	Subcutaneous	40 Milligram, 0.5 Day, 0.5 Mg/Kg		Mylan
	Midazolam			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Oral	400 Milligram, On The First Day, 0.5 Day		Mylan
	Hydroxychloroquine			S	Oral	200 Milligram, On Days 2-5, 0.5 Day		Mylan
	Piritramide			S	Unknown	Unk		Mylan
	Dexmedetomidine			S	Unknown	Unk		Mylan
	Nicardipine			C	Intravenous (not otherwise specified)	Unk		Mylan
	Amoxicillin/Clavulanic Acid			C	Unknown	1 Dosage Form, Q6h		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124277	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-MAPI_00010752			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Interstitial Lung	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Concordia

Disease; Vomiting	(Authorized Generic),Plaquenil					
	Leflunomide	S	Oral	10 Mg, Qd		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Qd		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124365	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810346		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	17.5 Mg		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124369	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810448		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124554	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810476			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810481			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Celebrex		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Bifidobacterium Bifidum		C	Unknown		Not Reported
	Loperamide		C	Oral		Not Reported
	Pantoprazole		C	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125121	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810417		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125122	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809616			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug	Methotrexate			S	Unknown	20 Milligram Daily;		Barr

Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125126	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810214		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125160	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810213		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	11.2 Milligram Daily;		Not Reported

Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Lyrica		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125174	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-24129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown. Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown. Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown. Solution		Not Reported

				Subcutaneous		
	Sulfasalazine	S	Oral	Unknown		Not Reported
	Methotrexate	C	Unknown	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125395	EXPEDITED (15-DAY)		DE, OT	PT-PFIZER INC-2020299925		89 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis; Electrocardiogram Qt Prolonged; Intestinal Ischaemia; Off Label Use; Product Use In Unapproved Indication; Septic Shock	Azithromycin			S	Oral	500 Mg, Once A Day		Pfizer
	Plaquinol			S	Oral	400 Mg, Once A Day (400 Mg Of12/12h In D0 And Then 200 Mg Of 12/12h)		Not Reported
	Plaquinol			S	Oral	200 Mg, Once A Day (400 Mg Of12/12h In D0 And Then 200 Mg Of 12/12h)		Not Reported
	Lactitol			C	Oral	Unk		Not Reported
	Potassium Dihydrogen Phosphate			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Calcium Gluconate			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Glucose			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Amiodarone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Chloride			C	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Oxazepam	C	Oral	Unk	Not Reported
	Esomeprazole	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Enoxaparin Sodium	C	Subcutaneous	Unk	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Amoxicillin + Clavulanic Acid	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Magnesium Sulfate	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Human Serum Albumin	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125397	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-063743		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18127804	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel Sureclick Pf Autoinj 50mg/Ml Amgen			S	Subcutaneous			Amgen
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	15853478	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634392-00		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	15935702	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657574-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown	500 Mg To 1000 Mg Twice Daily		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18125903	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811205		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Ergocalciferol	C	Unknown	Not Reported
	Folinic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18125910	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810509		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Desoximetasone	C	Oral		Not Reported
	Desoximetasone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18125996	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3476655-00		66 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral	400/100mg		Not Reported
	Plaquenil			S	Oral	In Total		Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass			C	Intravenous (not otherwise specified)	1.2 Gram 1x / 6h		Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass			C	Oral			Not Reported
	Enoxaparin Sodium			C				Not Reported
	Melatonin			C		As Required		Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810717		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	400 Milligram Daily;		Not Reported

	Hydroxychloroquine Sulfate		C	Unknown	400 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126032	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126102	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1810695			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C		25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126103	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1810496		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810705		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126110	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810709		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810704			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126150	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810707		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Desoximetasone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126446	EXPEDITED (15-DAY)		OT	NVSC2020BE220061			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia; Product Use In Unapproved Indication	Azathioprine			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126533	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810532			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126534	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811196			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126537	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Meloxicam			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810557		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126540	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1810725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126541	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810711		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126542	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810700			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Leflunomide			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126551	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1810504		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126571	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810485		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126574	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy;	Methotrexate			S	Unknown			Barr

Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra		S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126576	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810488		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18126577	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1810439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2020	18111177	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020ES215521		37 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Enanthema; Leukocytosis; Lymphadenopathy; Off Label Use; Purpura; Pyrexia; Rash Maculo-Papular; Transaminases Increased	Hydroxychloroquine			S	Unknown	200 Mg		Novartis
	Hydroxychloroquine			S				Novartis
	Lopinavir + Ritonavir			C	Unknown	Unk, 200/50 Mg		Not Reported
	Lopinavir + Ritonavir			C	Unknown	1 Df(200/50 Mg), Q12h		Not Reported
	Azithromycin			C	Unknown	250 Mg, Qd		Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	14161744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2014675			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated;	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Prefilled Syringe; Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Naprosyn	S	Oral		Not Reported
	Naprosyn	S	Oral		Not Reported
	Naprosyn	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	15007038	EXPEDITED (15-DAY)		OT	CA-ROCHE-2139011		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule	Actemra			S	Unknown	Solution For Injection In Pre-Filled Syringe		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	15354415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180456		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	15402622	EXPEDITED (15-DAY)		DE, HO, OT	CO-ACTELION-A-CH2018-179017		63 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Acute Oesophageal Mucosal Lesion; Angina Unstable; Anxiety; Arrhythmia; Asthenopia; Blood Creatinine Increased; Bronchitis; Cardiac Failure; Cardio-Respiratory Arrest; Chest Discomfort; Chest Pain; Choking; Chronic Kidney Disease; Coagulation Time Prolonged; Coagulopathy; Constipation; Diarrhoea; Discomfort; Dizziness; Dyspnoea; Ear Disorder; Eye Disorder; Fall; Fatigue; Feeling Abnormal; Fibromyalgia; Flatulence; Fluid Retention; Gait Disturbance; General Physical Health Deterioration; Haematemesis; Head Discomfort; Headache; Heart Disease Congenital; Hyponatraemia; Hypotension; Hysterectomy; Inflammation; Inflammation Of Wound; Intestinal Obstruction; Joint Swelling; Loss Of	Tracleer			S	Oral	62.5 Mg, Bid		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Riociguat			S	Unknown	Unk		Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Carvedilol			C				Not Reported
	Metoprolol			C				Not Reported

Control Of Legs; Malaise; Memory Impairment; Mitral Valve Calcification; Mitral Valve Disease; Musculoskeletal Pain; Nervous System Disorder; Pain In Extremity; Peripheral Swelling; Product Availability Issue; Pulmonary Artery Occlusion; Reflux Gastritis; Renal Disorder; Swelling; Swelling Face; Swelling Of Eyelid; Syncope; Tremor; Vasodilatation; Walking Aid User; Walking Disability; Wheelchair User

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	16031108	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059233			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd, Tablet		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Solution Intravenous		Not Reported
	Acetaminophen			C		2 Tablet Of 500 Mg, Qid		Not Reported
	Hydromorphone			C				Not Reported
	Hydrocortisone Valerate			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Lyderm [Fluocinonide]			C		Unk		Not Reported
	Myocrisin			C	Unknown	Unk Unk, 1 Every 2 Week		Not Reported

Naproxen	C	Unknown	250 Mg, Qd		Not Reported
Naproxen	C		Unk Unk, Unk		Not Reported
Prednisone	C	Unknown	10 Mg, Qd		Not Reported
Sodium Aurothiomalate	C		Cycle 1 Every Two Week		Not Reported
Hydromorphone Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	16139672	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1213		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral	Cyclical		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Cyclic		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Cyclic		Not Reported
Humira	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Azathioprine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Subcutaneous			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Apo-Azathioprine	S	Unknown			Not Reported
Apo-Azathioprine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	16199830	EXPEDITED (15-DAY)		DS, HO, OT	CA-009507513-1904CAN006247		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase; Aspartate Aminotransferase Increased; Asthenia; Asthma; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Body Temperature Decreased; Bone Lesion; C-Reactive Protein Abnormal; C-Reactive Protein	Fosamax			S	Unknown	70 Milligram, Qw (1 Every 1 Week)		Merck
	Fosamax			S	Unknown	Unk		Merck
	Fosamax			S	Unknown	70 Milligram, 4 Every 1 Week		Merck
	Fosamax			S	Unknown	70 Milligram		Merck
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form : Powder For Solution Intravenous		Not Reported
	Remicade			S	Unknown	Dosage Form : Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form : Powder For Solution Intravenous, Therapy Duration: 365.0		Not Reported

Increased; Chills; Condition Aggravated; Contraindicated Product Administered; Contusion; Cough; Deep Vein Thrombosis; Dermatitis; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Enthesopathy; Erythema; Fall; Fatigue; Gastric Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Granuloma Skin; Headache; Heart Rate Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Influenza; Infusion Related Reaction; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Muscular Weakness; Musculoskeletal Disorder; Musculoskeletal Stiffness; Mycotic Allergy; Nausea; Neoplasm Skin; Off Label Use; Pain; Pain In Extremity; Panniculitis; Peripheral Swelling; Product Use Issue; Productive Cough; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation				(Units Not Provided)	
	Actemra	S	Intravenous (not otherwise specified)	360.0 Milligram, Qm (1 Every 1 Month) (Also Reported As Every 4 Weeks)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	680.0 Milligram, 1 Every 1 Month(Also Reported As Every 4 Weeks), Dosage Form: Solution For Infusion	Not Reported
	Actemra	S	Unknown	680.0 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	2.68 Milligram, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	680 Milligram 1 Every 1 Months (Dosage Form: Not Specified)	Not Reported
	Actemra	S		360.0 Milligram	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, Qw (1 Every 1 Week)	Not Reported
	Alendronic Acid	S	Unknown	70.0 Milligram, 1 Every 1 Week	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram,Biw (2 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	25 Milligram (1 Every 2 Weeks)	Not Reported
	Enbrel	S	Unknown	50.0 Milligram, Qw(1 Every 1 Week)	Not Reported
	Enbrel	S	Subcutaneous	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Dosage	Not Reported

Rate Increased; Respiratory Tract Congestion; Rheumatoid Arthritis; Rheumatoid Nodule; Rhinorrhoea; Skin Necrosis; Skin Ulcer; Speech Disorder; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Humira	S	Subcutaneous	Form: Solution Subcutaneous 40.0 Milligram, 1 Every 2 Weeks, Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	360 Milligram 1 Every 1 Months	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	680 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram, Every 4 Weeks(1every4week)	Not Reported
	Methotrexate	S	Unknown	15.0 Milligram, (1 Every 4week)	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, (1 Every 4 Weeks)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, (1 Every 4 Weeks)	Not Reported

Methotrexate	S	Unknown	12.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	10.0 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Weks	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qm (1 Every 1 Month), Dosage Form: Solution Intramuscular	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qm (1 Every 1 Month),	Not Reported
Myochrysine	S	Intramuscular	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 2 Weeks	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Myochrysine	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	780.0 Milligram, Qw(1every1week)	Not Reported
Orencia	S	Unknown	760 Milligram, Qw (1 Every 1 Week)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	360.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Simponi	S	Subcutaneous	680.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Simponi	S	Subcutaneous	Dosage Form Solution	Not Reported

			Subcutaneous	
Rituxan	S	Intravenous drip	1000 Milligram, 2 Every1 Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram (1 Every 12hour(S)/(2 Every 1 Day))	Not Reported
Benadryl	S	Unknown	Dosage Form Not Specified	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Dosage Form: Not Specified	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Sulfasalazine	S	Endocervical	Dosage Form Reported As Not Specified	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk, Single-Use Pre-Filled Syringe, Dosage Form Reported As Solution Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	680 Milligram, 1 Every 4 Weeks	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Months	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Tocilizumab	S	Unknown	388 Unk	Not Reported
Etanercept	S	Unknown	25 Milligram 1 Every 1	Not Reported

			Wek	
Etanercept	S	Unknown	25.0 Milligram 2 Every 1 Wek	Not Reported
Etanercept	S	Unknown	50 Milligram 1 Every 1 Wek	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S			Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qm	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qm	Not Reported
Ergocalciferol	S	Unknown	Dosage Form: Not Specified	Not Reported
Pantoprazole	S	Unknown	Dosage Form: Not Specified	Not Reported
Apo Ibuprofen	S	Oral	Unk	Not Reported
Apo Ibuprofen	S			Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram 2 Every 1 Days	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram	Not Reported
Ibuprofen	S		600 Milligram; Dosage Form: Not Specified	Not Reported
Ibuprofen	S	Oral	600 Milligram 1 Every 1 Days	Not Reported
Ibuprofen	S	Oral	Unk, Qd	Not Reported
Stelara	S	Subcutaneous	Unk, Dosage Form Reported As Solution Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Otezla	S	Unknown		Not Reported
Rituximab	S	Intravenous (not	1000 Milligram, 2 Every 1	Not Reported

		otherwise specified)	Days (1 Every 12 Hours)	
Rituximab	S			Not Reported
Cyclosporine	S	Unknown	150.0 Milligram, Q24h (1every24hours) (1 Every 1 Day), Dosage Form: Not Specified	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Motrin (Ibuprofen)	S		600 Milligram, Qd	Not Reported
Motrin (Ibuprofen)	S		600 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Q24h(1every24 Hours) (1 Every 1 Day)	Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h (1 Every 2 Hours)	Not Reported
Prednisone	C	Unknown	10.0 Milligram	Not Reported
Prednisone	C	Unknown	20.0 Milligram	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Prednisone	C	Unknown	Dosage Form: Not Specified	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Xeljanz	C	Oral	5.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	10.0 Milligram 1 Every 1 Days, Dosage Form: Not Specified	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Naproxen	C	Unknown	Dosage Form: Not Specified	Not Reported

Plaquenil	C	Unknown		Not Reported
Symbicort	C	Unknown		Not Reported
Tramadol Hydrochloride	C	Unknown		Not Reported
Colchicine	C	Oral	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown		Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Uloric	C	Unknown	80 Milligram 2 Every 1 Days	Not Reported
Uloric	C	Unknown	80 Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	16703865	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA211151			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S		20 Mg, Unk		Sanofi
	Alendronate Sodium			S	Unknown	70 Mg, Qw		Not Reported
	Alendronic Acid			S		70 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	12 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	12 Mg, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Enbrel	S	Unknown	25 Mg, Qow	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q15d	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	780 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Actemra	S	Unknown	680 Mg, Q4w	Not Reported
	Actemra	S	Unknown	360 Mg, Qm	Not Reported
	Tocilizumab	S		360 Mg, Qm	Not Reported
	Tocilizumab	S		680 Mg, Qm	Not Reported
	Xeljanz	C			Not Reported
	Ciclosporin	C		150 Mg, Qd	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17042231	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465088		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17366989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020043725		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Milligram 4 Years		Pfizer
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

Otezla	S	Oral	Unk		Not Reported
Otezla	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
Cimzia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17425150	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202002000774			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Anxiety; Cell Death; Cholestasis; Dyspnoea; Eosinophil Count Increased; Eosinophil Count Increased; Epidermal Necrosis; Pustular Psoriasis; Pyrexia; Rash; Rash Pruritic; Rash Pustular; Skin Exfoliation; Toxic Skin Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Levothyrox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17710765	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020055142		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline

Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cetirizine Hydrochloride	S			Glaxosmithkline
	Cortisone Acetate	S	Unknown	25 Mg	Glaxosmithkline
	Cortisone Acetate	S	Unknown	25 Milligram	Glaxosmithkline
	Desoximetasone	S	Oral	And Oral	Glaxosmithkline
	Diclofenac	S	Unknown	50 Milligram	Glaxosmithkline
	Folic Acid	S	Subcutaneous	1 Milligram	Glaxosmithkline
	Folic Acid	S	Oral	25 Mg	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Topicort	S	Subcutaneous	Unk	Glaxosmithkline
	Topicort	S	Topical	Unk	Glaxosmithkline
	Stelara	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Unknown	400 Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Plaquenil (Hydroxychloroquine)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

Sarilumab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	40 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Methotrexate	C	Oral	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	C	Oral	25 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	C	Oral	25 Milligram	Not Reported
Xeljanz	C	Unknown	5 Milligram, Once Daily (Qd)	Not Reported
Xeljanz	C	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17763247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594680		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Elavil (Canada)			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Infliximab	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Medroxyprogesterone Acetate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Naprosyn	S	Unknown			Not Reported
Oxycodone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Etanercept	S	Unknown			Not Reported
Amitriptyline	S	Unknown			Not Reported
Cyclosporine A	C				Not Reported
Depo Provera	C	Intramuscular	Sterile Aqueous Suspension		Not Reported
Kineret	C	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17787135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593552		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride;Perphenazine			S	Unknown			Not Reported

Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Amitriptyline Hydrochloride;Perphenazine	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Diclo	S	Unknown	Tablet (Enteric Coated)	Not Reported
	Apo-Diclofenac	S	Topical		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arthrotec	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S			Not Reported
	Celecoxib	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported

Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Misoprostol	S	Unknown	Not Reported
Naprosyn	S	Unknown	Not Reported
Nifedipine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Winpred	S	Unknown	Not Reported
Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17793971	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17836482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602499		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Orencia	S	Subcutaneous	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17843218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606612		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17848609	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606875			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Simponi	S	Subcutaneous		Not Reported
Arava	S	Oral		Not Reported
Sulfasalazine	S	Subcutaneous		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17869727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Risedronate Sodium			C	Unknown			Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	17888710	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18014878	EXPEDITED (15-DAY)		HO, OT	NVSC2020PT196035		52 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Pneumonia; Product Use In Unapproved Indication; Respiratory Failure	Azithromycin			S	Unknown	500 Mg(On The First Day)		Novartis
	Azithromycin			S	Unknown	250 Mg(Daily On The Following 4 Days)		Novartis
	Atenolol			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg(Twice A Day In First Day)		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg(Twice A Day On Next 7 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18070196	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-192093		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency;	Methotrexate			S				Accord

Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S			Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Infliximab	S			Not Reported
	Orencia	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S			Not Reported
	Triamcinolone	C			Not Reported
	Prednisone	S	Oral	2 Every 1 Days	Not Reported
	Methotrexate	S	Subcutaneous	12 Every 2 Weeks	Accord
	Enbrel	S		1 Every 1 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18083674	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-193287		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Chorioretinitis; Leukopenia; Macular Degeneration; Necrotising Retinitis	Mycophenolic Acid			S				Accord
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18087758	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2020283115		84 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis;	Azithromycin			S	Intravenous (not	500 Mg, 1x/Day		Pfizer

Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication; Product Use Issue				otherwise specified)		
	Plaquinol		S	Oral	400 Mg, 2x/Day(400mg 12 / 12h In D0 And Then 200mg 12 / 12h)	Not Reported
	Plaquinol		S	Oral	200 Mg, 2x/Day(400mg 12 / 12h In D0 And Then 200mg 12 / 12h)	Not Reported
	Sertraline		C	Oral	50 Mg, 1x/Day	Not Reported
	Oxazepam		C	Oral	15 Mg, 1x/Day	Not Reported
	Omeprazole		C	Oral	20 Mg, 1x/Day	Not Reported
	Piperacillin + Tazobactam		C	Intravenous (not otherwise specified)	9000 Mg, 1x/Day	Not Reported
	Nifedipine		C	Oral	60 Mg, 1x/Day	Not Reported
	Enoxaparin Sodium		C	Subcutaneous	120 Mg, 1x/Day	Not Reported
	Quetiapine		C	Oral	25 Mg, 1x/Day	Not Reported
	Captopril		C	Oral	25 Mg, As Needed	Not Reported
	Indapamide		C	Oral	2.5 Mg, 1x/Day	Not Reported
	Candesartan		C	Oral	32 Mg, 1x/Day	Not Reported
	Cefazolin		C	Intravenous (not otherwise specified)	3000 Mg, 1x/Day	Not Reported
	Amiodarone		C	Oral	200 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18089482	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1806248		54 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatocellular Injury	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Plaquinol			S	Oral	400mg 12 / 12h In D0 And Then 200mg 12 / 12h		Not Reported
	Calcium Polystyrene Sulfonate			C		2gram		Not Reported
	Dolutegravir + Abacavir +			C	Oral	1 Dosage Forms		Not Reported

	Lamivudina					
	Ceftriaxone		C	Intravenous (not otherwise specified)	2000 Mg	Not Reported
	Bisacodyl		C	Oral	5 Mg	Not Reported
	Potassium Dihydrogen Phosphate		C	Intravenous (not otherwise specified)	10 Milliequivalents	Not Reported
	Paracetamol		C	Oral	1000 Mg,As Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18094734	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1806889		56 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment	Azithromycin			S	Oral	500 Mg		Not Reported
	Plaquinol			S	Oral	400mg 12 / 12h In D0 And Then 200mg 12 / 12h, Unit Dose: 400mg		Not Reported
	Flucloxacillin			C	Intravenous (not otherwise specified)	12000 Mg		Not Reported
	Paracetamol			C	Oral	1000 Mg		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2000 Mg		Not Reported
	Metamizole Magnesium			C	Oral	575 Mg		Not Reported
	Metamizole Magnesium			C	Intravenous (not otherwise specified)	2000 Mg		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	1000 Ml		Not Reported
	Gentamicin			C	Intravenous (not otherwise specified)	240 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127047	EXPEDITED (15-DAY)		OT	CH-LUPIN PHARMACEUTICALS		79 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk (Total 1600 Mg)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127162	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-037545		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Bradycardia; Dizziness; Drug Interaction; Fatigue; Hypotension	Alendronate Sodium			S	Oral	70 Milligram, Every Week (By Mouth)		Aurobindo
	Dofetilide			S	Oral	125 Microgram, Two Times A Day		Aurobindo
	Dofetilide			S	Oral	250 Microgram, Two Times A Day		Aurobindo
	Lisinopril			S	Oral	10 Milligram, Once A Day (By Mouth)		Aurobindo
	Polyethylene Glycol 3350 Powder For Oral Solution 17g			S	Unknown	17 Gram, Once A Day (Dissolve 1 Scoop In Beverage Once Daily		Aurobindo
	Calcium & Vitamin D3			S	Oral	Unk, Once A Day (600 Mg/200 Iu, By Mouth)		Not Reported
	Chlorthalidone			S	Oral	25 Milligram, Once A Day (By Mouth)		Not Reported
	Cholecalciferol			S	Oral	1000 International Unit, Once A Day (By Mouth)		Not Reported
	Estrogens Conjugated			S	Vaginal	0.625 Milligram/Gram (At Bedtime)		Not Reported
	Fluticasone			S		Unk, Once A Day (One Spray Daily In Each Nostril)		Not Reported

Fluticasone;Salmeterol	S	Unknown	Unk , Two Times A Day (250/50 Mcg)		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Once A Day (By Mouth)		Not Reported
Sulfasalazine	S	Oral	500 Milligram, Two Times A Day (By Mouth)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127205	EXPEDITED (15-DAY)		HO	US-ROCHE-2655231			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Neonatal Respiratory Distress Syndrome; Premature Baby	Actemra			S	Transplacental			Not Reported
	Ceftriaxone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Heparin			S	Transplacental			Not Reported
	Betamethasone			S	Transplacental	Single Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127255	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-04297		29 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Maternal Exposure During Pregnancy; Off Label Use; Premature Delivery	Oseltamivir			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ribavirin			S	Unknown	Unk		Not Reported
	Arbidol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127258	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-		75 YR	Female	TUR

2020RR-256388

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Oseltamivir			S	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127260	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-04296		26 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Maternal Exposure During Pregnancy; Off Label Use; Premature Delivery	Oseltamivir			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ribavirin			S	Unknown	Unk		Not Reported
	Arbidol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127338	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-063645			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Ilaris	S	Unknown	Unk		Not Reported
	Ilaris	S				Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Leflunomide	S				Not Reported
	Methotrexate	S	Intra-arterial	Unk		Not Reported
	Methotrexate	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127354	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04185		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Aztreonam			C	Unknown	Unk		Not Reported
	Filgrastim			C	Subcutaneous	480 Microgram (4.8microgram/Kg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127381	EXPEDITED (15-DAY)		OT	KR-LUPIN PHARMACEUTICALS		68 YR	Male	KOR

INC.-2020-04353

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Ceftazidime			S	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			C	Unknown	1 Dosage Form, Bid		Not Reported
	Colistin			C		75 Milligram, Bid		Not Reported
	Meropenem			C	Unknown	1 Gram, Tid		Not Reported
	Dexamethasone			C	Unknown	20 Milligram, Unk		Not Reported
	Dexamethasone			C	Unknown	10 Milligram, Unk		Not Reported
	Dexamethasone			C	Unknown	Unk (Tapered In Half Every 5 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127391	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04516		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (For First Day)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (For 4 Days)		Lupin
	Piperacillin & Tazobactam			C	Unknown	Unk		Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Filgrastim			C	Subcutaneous	480 Microgram (7.8microgram/Kg) (One Dose Each On Days 5 And Day 8)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127397	EXPEDITED (15-DAY)		OT	CA-ACCORD-194501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127402	EXPEDITED (15-DAY)		OT	CA-ACCORD-194533		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Oral			Accord
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Etanercept			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Dosage Form:Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown	Not Specified	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form:Powder For Solution Intravenous	Not Reported
	Desoximetasone	C		Not Specified	Not Reported
	Methotrexate	S	Oral		Accord
	Methotrexate	S	Oral	Not Specified	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127418	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04517		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (For The First Day)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (For Four Days)		Lupin
	Filgrastim			C	Subcutaneous	(3.9 Microgram/Kg) One Dose Each On Days 1 And Day 2		Not Reported
	Cefepime			C	Unknown	2 Gram, Tid (Every 8 Hour)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127427	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04359		54 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Ketorolac			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	5-10 Mg, Qd		Not Reported

	Vitamin B Complex		C	Unknown	Unk	Not Reported
	Bromhexine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127428	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04357		35 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Prednisolone			C	Unknown	5-10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127429	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04356		30 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Methylprednisolone			C	Unknown	Unk (Pulse Therapy)		Not Reported
	Prednisolone			C	Unknown	5-10 Mg, Qd		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127430	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04358		48 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Prednisolone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127436	NON-EXPEDITED			US-ADVANZ PHARMA-202007007660			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Zinc			S		Unk		Not Reported
	Zithromax			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127437	NON-EXPEDITED			US-ADVANZ PHARMA-202007007663			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127481	EXPEDITED (15-DAY)		OT	CA-ACCORD-194518			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	1 Every 1 Weeks		Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Prefilled Syringe, 1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, 1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127482	EXPEDITED (15-DAY)		OT	CA-ACCORD-194503		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127483	EXPEDITED (15-DAY)		OT	CA-ACCORD-194517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	1 Every 1 Weeks		Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Sublingual	Solution Subcutaneous, Single-Use Prefilled Syringe 1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous 1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Infliximab		S	Intravenous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127507	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04360		42 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Prednisolone			C	Unknown	Unk		Not Reported
	Co-Amoxiclav [Amoxicillin;Clavulanate Potassium]			C	Unknown	625 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127527	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202008007662			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Covid-19; Feeling Hot; Immunosuppression; Insomnia; Sjogren'S Syndrome	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Rinvoq			S	Oral	15 Mg,1 In 1 D		Not Reported
	Rinvoq			S	Oral	15 Mg,1 In 1 D		Not Reported
	Meloxicam			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127572	EXPEDITED (15-DAY)		CA, HO	CA-TEVA-2020-CA-1811362			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr

Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Celebrex	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular	7.1429 Milligram Daily; Solution Intramuscular	Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Isoniazid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18127575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811571		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18128205	EXPEDITED (15-DAY)		HO	PT-TEVA-2020-PT-1809485		51 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Electrocardiogram Qt Prolonged; Hepatic Enzyme Increased	Hydroxychloroquine		S	Oral	200mg 12/12h, Unit Dose: 400 Mg	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18128494	EXPEDITED (15-DAY)		HO	IR-LUPIN PHARMACEUTICALS INC.-2020-04341		30 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Metabolism Disorder; Drug Interaction; Gastrointestinal Disorder; Osteoporosis	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Calcium Acetate			S	Unknown	Unk		Lupin
	Calcium Acetate			S				Lupin
	Mycophenolate Mofetil			S	Unknown	2 Gram, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	500 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	15 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	5 Milligram, Qd		Not Reported
	Vitamin D [Colecalciferol]			S	Unknown	Unk		Not Reported
	Vitamin D [Colecalciferol]			S				Not Reported
	Forteo			S	Subcutaneous	20 Microgram Qd		Not Reported
	Azathioprine			S	Unknown	2.5 Milligram/Kilogram Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18128510	EXPEDITED (15-DAY)		OT	CH-LUPIN PHARMACEUTICALS INC.-2020-04186		70 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Total Dose 1600 Mg		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18128549	EXPEDITED (15-DAY)		DE, LT	US-PFIZER INC-2020300186		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18128905	NON-EXPEDITED			US-PFIZER INC-2020302687		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sunburn	Doxycycline Hyclate			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129028	EXPEDITED (15-DAY)		OT	CA-ACCORD-194520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use,Solution Subcutaneous		Not Reported
	Cortisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)	
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129136	EXPEDITED (15-DAY)		OT	CA-ACCORD-194295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129194	EXPEDITED (15-DAY)		HO	CA-ACCORD-194296			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Triamcinolone			S				Not Reported

Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Sulfasalazine		S	Oral	1 Every 1 Days	Not Reported
	Prednisone		S	Oral	2 Every 1 Days	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Naproxen		S			Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Hydroxychloroquine		S	Oral	1 Every 1 Days	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Anakinra		S	Subcutaneous	1 Every 1 Days	Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral	2 Every 1 Days	Not Reported
	Infliximab		S		1 Every 1 Weeks	Not Reported
	Enbrel		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129210	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1809742			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

	Rituximab	S	otherwise specified) Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129501	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-005759			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dental Care; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete; Vomiting; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	300 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	20 Mg, Weekly		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Adalimumab			S	Subcutaneous	Unk,Qow		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Calcium			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported
	Naprosyn			C		Unk		Not Reported
	Pantoprazole Sodium			C		Unk		Not Reported
	Potassium			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129979	EXPEDITED (15-DAY)		HO	CA-ACCORD-194260			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous	1 Every 1 Days		Accord
	Triamcinolone			S	Oral			Not Reported
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported
	Prednisone			S	Oral	2 Every 1 Months		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Naproxen			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 2 Weeks		Not Reported
	Prednisone			S	Oral	2 Every 1 Months		Not Reported
	Infliximab			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129980	EXPEDITED (15-DAY)		HO	CA-ACCORD-194261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Orencia			S				Not Reported
	Leflunomide			S				Not Reported
	Infliximab			S	Intravenous (not	1 Every 1 Weeks		Not Reported

Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Humira		S	Subcutaneous (not otherwise specified)	1 Every 1 Weeks	Not Reported
	Enbrel		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Actemra		S			Not Reported
	Abatacept		S			Not Reported
	Rituximab		S			Not Reported
	Infliximab		S			Not Reported
	Humira		S			Not Reported
	Enbrel		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18129981	EXPEDITED (15-DAY)		HO	CA-ACCORD-194498		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Gabapentin			S	Oral	2 Every 1 Days		Not Reported
	Myochrysine			S	Intramuscular	1 Every 3 Weeks, Solution Intramuscular		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 3 Weeks		Not Reported
	Oxycodone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported

Lesion; Treatment Failure	Arava	S	Oral	1 Every 1 Months	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Biotin	C			Not Reported
	Cyanocobalamin	C			Not Reported
	Tocopherol	C		D-Alpha Tocopherol	Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	C			Not Reported
	Iron	C			Not Reported
	Iron	C			Not Reported
	Folic Acid	C			Not Reported
	Lomotil	C			Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Nicotinamide	C			Not Reported
	Nortriptyline	C			Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C			Not Reported
	Pyridoxine	C			Not Reported
	Retinol	C			Not Reported
	Riboflavin	C			Not Reported
	Risedronic Acid	C			Not Reported
	Ascorbic Acid	C			Not Reported
	Thiamine	C			Not Reported
	Trazodone	C			Not Reported
	Tylenol	C			Not Reported
	Retinol	C			Not Reported
	Thiamine	C			Not Reported
	Ascorbic Acid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130021	EXPEDITED (15-DAY)		OT	CA-ACCORD-194523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Pantoprazole	S	Oral	1 Every 1 Days	Not Reported
	Diclofenac	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Leucovorin Calcium	S	Oral	1 Every 1 Weeks	Not Reported
	Meloxicam	S	Oral	1 Every 1 Days	Not Reported
	Otezla	S	Unknown		Not Reported
	Cosentyx	S	Oral	1 Every 1 Months	Not Reported
	Synthroid	S	Unknown		Not Reported
	Mar-Pantoprazole	C	Unknown		Not Reported
	Mometasone	C	Unknown		Not Reported
	Fluticasone	C	Respiratory (inhalation)		Not Reported
	Diltiazem	C	Oral		Not Reported
	Premarin	C	Unknown		Not Reported
	Salbutamol	C	Respiratory (inhalation)		Not Reported
	Tramadol	C	Oral	1 Every 1 Days	Not Reported
	Methotrexate	S		1 Every 1 Weeks	Accord
	Methotrexate	S	Oral	1 Every 1 Weeks	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130023	EXPEDITED (15-DAY)		HO	CA-ACCORD-194499		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Gabapentin			S	Oral	2 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported

Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celebrex	S	Oral		Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Oxycontin	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Fentanyl	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Aclasta	C			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	C			Not Reported
	Iron	C			Not Reported
	Genteal	C			Not Reported
	Lomotil	C			Not Reported
	Nasonex	C			Not Reported
	Nortriptyline	C			Not Reported
	Prednisone	C			Not Reported
	Risedronic Acid	C			Not Reported
	Trazodone	C			Not Reported
	Tylenol	C			Not Reported
	Orencia	S	Subcutaneous	1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130915	EXPEDITED (15-DAY)		HO, LT, OT	BN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-257006		60 YR	Female	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Condition Aggravated; Electrocardiogram Qt Prolonged; Off Label Use	Amoxicillin, Clavulanic Acid			S	Intravenous (not otherwise specified)	1200 Milligram, Tid		Ranbaxy
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun

Lopinavir + Ritonavir	S	Unknown	Lopinavir 400 Mg/Ritonavir 100 Mg (Twice Daily)		Not Reported
Meropenem	S	Unknown	1000 Milligram, Tid		Not Reported
Meropenem	S				Not Reported
Oseltamivir	S	Unknown	75 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18131275	EXPEDITED (15-DAY)		HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-002510			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Palpitations	Hydroxychloroquine Sulfate			S	Oral	Unk		Ipca
	Mullein Extract			C	Unknown	Unk		Not Reported
	Selenium			C	Unknown	Unk		Not Reported
	Krill Oil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18131339	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130808			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Arava			S	Oral	10 Mg, Q3m		Sanofi
	Arava			S	Oral	10 Mg, Q3w		Sanofi
	Arava			S	Oral	200 Mg, Qow		Sanofi
	Arava			S	Oral	10 Mg, Qm		Sanofi
	Arava			S	Oral	10 Mg		Sanofi
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Arava			S	Oral	10 Mg, Q2m		Sanofi
	Plaquenil			S		Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi

	Methotrexate	S	Unknown	12.5 Mg	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk, 1 Every 2 Years	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intramuscular	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18131591	EXPEDITED (15-DAY)		OT	CA-ROCHE-2655547		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium Carbonate/Vitamin D3			C				Not Reported
	Hydrocortisone			C				Not Reported

	Pantoloc [Pantoprazole]	C			Not Reported
	Prednisone	C			Not Reported
	Tylenol Arthritis Pain	C	2.0 Dosage Forms		Not Reported
	Xarelto	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18131718	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-064286		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Pulmonary Fibrosis; Treatment Failure	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Milligram		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	13109301	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-065623		365 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S				Bristol Myers Squibb

Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Triamcinolone Acetonide	S			Bristol Myers Squibb
	Triamcinolone Acetonide	S			Bristol Myers Squibb
	Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Bristol Myers Squibb
	Triamcinolone Acetonide	S			Bristol Myers Squibb
	Triamcinolone Acetonide	S			Bristol Myers Squibb
	Triamcinolone Acetonide	S			Bristol Myers Squibb
	Enbrel	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Enbrel	S		12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Unknown	3 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 2 Every 1 Week	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported

Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Milligram	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S			Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	50 Milligram, Qwk	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Tocilizumab	S			Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Triamcinolone	S			Not Reported
Triamcinolone	S			Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S			Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70.0 Gram	Not Reported
Gamastan	S	Intramuscular	70 Gram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Dosage Form	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	25 Milligram(2 Every 1 Week)	Not Reported
Etanercept	S		12.5 Milligram, Qwk	Not Reported

	Triamcinolone Hexacetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	13244457	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Apotex
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	13519392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038157		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	15558530	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018149419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Otezla			S	Unknown	Unk		Amgen
	Otezla			S	Oral	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported

Stelara	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Morphine	S	Unknown	Unk		Not Reported
Dilaudid	C		Unk		Not Reported
Wellbutrin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	15622617	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555903-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	15623907	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554647-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased;	Humira			S	Subcutaneous			Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Imitrex	C	Unknown	Not Reported

	Sumatriptan		C	Unknown	Not Reported
	Amitriptyline		C		Not Reported
	Tofacitinib		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	15668052	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570500-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported
	Synthroid			C				Not Reported
	Restasis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	15715431	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018510528			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	15949376	EXPEDITED (15-DAY)		OT	PHHY2019US027075		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hellp Syndrome; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Hydroxychloroquine	S	Unknown	Unk		Novartis
	Hydroxychloroquine	S				Novartis
	Low Molecular Weight Heparin	S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin	S				Not Reported
	Aspirin	S	Unknown	Unk		Not Reported
	Aspirin	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	16300431	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121442			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Oral	100 Mg		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	16913149	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4155		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Cataract; Crepitations; Deformity; Diarrhoea;	Actemra			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Synovial Cyst; Synovitis; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; Viral Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Humira	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17283057	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020020262			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Sulfasalazine	S	Unknown	Unk		Pfizer
	Arava	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Cosentyx	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Otezla	S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous drip	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17491790	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005553			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Methotrexate			S	Unknown	15 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk, Single Use Prefilled Syringe		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Arava			S	Endocervical	20 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	567 Mg, Monthly		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

Celebrex	C				Not Reported
Inflectra	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17718313	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000337			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pneumonia Bacterial; Pneumonia Bacterial; Staphylococcal Bacteraemia	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Validus
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Validus
	Hydroxychloroquine Sulfate			S	Nasal	600 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Nasal	400 Mg, Qd		Not Reported
	Spiramycin			S	Nasal	6 Mu, Qd		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17749417	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591882			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17806260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598086		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Peripheral Swelling; Rash; Tendon Disorder	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17808262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Oral Discomfort; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

	Cimzia			S	Subcutaneous					Not Reported
	Enbrel			S	Unknown					Not Reported
	Humira			S	Subcutaneous					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Leflunomide			S	Unknown					Not Reported
	Methotrexate			S	Subcutaneous					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported
	Sarilumab			S	Unknown					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported
	Tofacitinib			S	Unknown					Not Reported
	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17818370	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Rituxan			S	Intravenous drip			Not Reported
	Cellcept			S	Unknown			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Pantoprazole			C				Not Reported
	Acetaminophen			C				Not Reported
	Actonel			C				Not Reported
	Amiodarone			C				Not Reported

Diphenhydramine	C			Not Reported
Eprex	C	Intravenous (not otherwise specified)		Not Reported
Escitalopram	C			Not Reported
Hydrochlorothiazide	C			Not Reported
Insulin Lispro	C			Not Reported
Januvia	C			Not Reported
Metformin	C			Not Reported
Methylprednisolone	C			Not Reported
Metoprolol	C			Not Reported
Pantoloc	C			Not Reported
Piperacillin/Tazobactam	C			Not Reported
Potassium Chloride	C			Not Reported
Risedronate Sodium	C			Not Reported
Slow-K	C			Not Reported
Tylenol	C			Not Reported
Ventolin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17820092	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601286		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S	Unknown	Gold (198 Au) Colloidal		Not Reported

Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

	Hydroxychloroquine Sulfate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17882858	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3437539-00		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyshidrotic Eczema; Eczema; Off Label Use; Pruritus	Kaletra 200/50			S	Oral	200 Mg/50 Mg		Not Reported
	Azithromycin			S	Oral			Not Reported
	Enoxaparin Sodium			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17920890	EXPEDITED (15-DAY)		LT, OT	ES-CIPLA LTD.-2020ES04114			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Disorientation; Hyperbilirubinaemia; Liver Function Test Abnormal; Urinary Retention	Levofloxacin			S	Unknown	500 Milligram, Bid (500 Mg / 12 Hours)		Cipla
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	800 Mg 1 Day + 400 Mg The Rest		Not Reported
	Lopinavir + Ritonavir			S	Unknown	Unk, 200/20, Qid, Four Times A Day		Not Reported
	Omeprazol [Omeprazole]			C	Unknown	Unk, 1/24		Not Reported
	Urbason [Methylprednisolone]			C	Unknown	40 Milligram, Every 8 Hours, At 5 Days Every 12		Not Reported
	Pulmicort			C	Unknown	Unk, Tid, 2 Puff Every 8 Hours		Not Reported
	Ventolin [Salbutamol]			C	Unknown	Unk		Not Reported
	Clexane			C	Unknown	Unk, 40/ 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	17988389	EXPEDITED (15-DAY)		OT	CA-ACCORD-188181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringes		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18067880	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1066162		86 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Nausea; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd 500mg 1x/Dia		Mylan
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Total 500mg 1x/Dia		Mylan
	Plaquinol			S	Oral	400mg 12/12h Em D0 E Depois 200mg 12/12h		Mylan
	Potassium Chloride			C	Intravenous (not otherwise specified)	40 Milliequivalent, Bid		Mylan
	Escitalopram			C	Oral	10 Milligram, Qd		Mylan
	Metoclopramide			C	Intravenous (not otherwise specified)	Sos Até Ao Máximo 30 Mg/Dia		Mylan

Enoxaparin Sodium	C		40 Milligram, Qd	Mylan
Bromazepam	C	Oral	Sos Até 1,5 Mg/Dia	Mylan
Amlodipine	C	Oral	5 Milligram, Qd	Mylan
Pantoprazole	C	Oral	20 Milligram, Qd	Mylan
Furosemide	C	Oral	40 Milligram, Qd	Mylan
Losartan + Hidroclorotiazida	C	Oral	1 Dosage Form, Qd	Mylan
Paracetamol	C	Intravenous (not otherwise specified)	Sos	Mylan
Piperacilina + Tazobactam	C	Intravenous (not otherwise specified)	18000 Milligram, Qd	Mylan
Acetylsalicylic Acid	C	Oral	100 Milligram, Qd	Mylan
Potassium Chloride	C	Oral	1200 Milligram, Qd	Mylan
Gabapentin	C	Oral	200 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18077208	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2020278256		86 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Single		Pfizer
	Plaquinol			S	Oral	400mg 12 / 12h In D0		Not Reported
	Plaquinol			S	Oral	200mg 12 / 12h		Not Reported
	Azithromycin			C	Oral	500 Mg, 1x/Day		Not Reported
	Potassium Chloride			C	Intravenous (not otherwise specified)	40 Meq, 2x/Day (Every 12 Hours)		Not Reported
	Escitalopram			C	Oral	10 Mg, Daily		Not Reported
	Metoclopramide			C	Intravenous (not otherwise specified)	Sos Up To A Maximum Of 30 Mg / Day		Not Reported
	Enoxaparin Sodium			C		40 Mg, Daily		Not Reported
	Bromazepam			C	Oral	As Needed (Sos Up To 1.5 Mg / Day)		Not Reported

Amlodipine	C	Oral	5 Mg, Daily		Not Reported
Pantoprazole	C	Oral	20 Mg, Daily		Not Reported
Furosemide	C	Oral	40 Mg, Daily		Not Reported
Losartan/Hydrochloorthiazide	C	Oral	1 Df, Daily		Not Reported
Paracetamol	C	Intravenous (not otherwise specified)	As Needed		Not Reported
Piperacillin + Tazobactam	C	Intravenous (not otherwise specified)	18000 Mg, Daily		Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg, Daily		Not Reported
Potassium Chloride	C	Oral	1200 Mg, Daily		Not Reported
Gabapentin	C	Oral	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18105400	EXPEDITED (15-DAY)		OT	CA-ACCORD-193791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Product Use Issue	Methotrexate			S	Oral			Accord
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Also Received 1 Every 1 Day Of Unknown Dose.		Not Reported
	Remicade			S	Unknown	Dosage Form: Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Folic Acid			C		Not Specified		Not Reported
	Prednisone			C	Oral	Not Specified		Not Reported
	Prednisone			C		Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18110575	EXPEDITED (15-DAY)		DE, OT	PT-MYLANLABS-2020M1068912		89 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd (500mg/Dia)		Mylan
	Hydroxychloroquine			S	Oral	400mg De 12/12h Em D0 E Depois 200mg De 12/12h		Mylan
	Plaquinol			S	Oral	400mg De 12/12h Em D0 E Depois 200mg De 12/12h		Mylan
	Furosemide			C	Intravenous (not otherwise specified)	Unk		Mylan
	Amiodarone			C	Intravenous (not otherwise specified)	Unk		Mylan
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	Unk		Mylan
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Mylan
	Meropenem			C	Intravenous (not otherwise specified)	Unk		Mylan
	Enoxaparin Sodium			C	Subcutaneous	Unk		Mylan
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Mylan
	Sodium Chloride			C	Intravenous (not otherwise specified)	Unk		Mylan
	Lactitol			C	Oral	Unk		Mylan
	Calcium Gluconate			C	Intravenous (not otherwise specified)	Unk		Mylan
	Glucose			C	Intravenous (not otherwise specified)	Unk		Mylan
	Human Serum Albumin			C	Intravenous (not otherwise specified)	Unk		Mylan
	Oxazepam			C	Oral	Unk		Mylan
	Potassium Dihydrogen Phosphate			C	Intravenous (not otherwise specified)	Unk		Mylan

	Esomeprazole	C	Intravenous (not otherwise specified)	Unk		Mylan
	Paracetamol	C	Intravenous (not otherwise specified)	Unk		Mylan
	Amoxicilina + Ac.Clavulanico	C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132121	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-256073		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, 1dose/12hour		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, 1dose/12hour		Ipca
	Methylprednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132163	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-MAPI_00012350			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Concordia
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132229	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-257023		68 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132232	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-257019		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132311	EXPEDITED (15-DAY)		HO, OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-256586		68 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lopinavir/Ritonavir			S	Unknown	400/100 Mg Every 12 Hours		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Meropenem			C	Unknown	1 Gram Every 8 Hours		Not Reported
	Dexamethasone			C	Unknown	20 Mg For 5 Days, Then 10 Mg For 5 Days, And Tapered In Half Every 5 Days		Not Reported
	Colistin			C	Unknown	Inhalation (75 Mg Every 12 Hours)		Not Reported
	Heparin			C	Intravenous (not			Not Reported

					otherwise specified)					
	Ceftazidime			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132314	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811603		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132315	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	420 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

Acetaminophen	C	Unknown	Not Reported
Caffeine	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Dorzolamide Hydrochloride	C	Ophthalmic	Not Reported
Folic Acid	C	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Meprobamate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported
Timolol Maleate	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132317	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811370		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132333	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132401	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2020-04320		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132607	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-256808		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis Infective; Condition Aggravated; Drug Resistance; Drug-Induced Liver Injury; Off Label Use	Meropenem			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Sun
	Linezolide			S	Intravenous (not	600 Milligram, Bid		Not Reported

			otherwise specified)		
	Linezolide	S			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Tid	Ipca
	Norepinephrine	S	Unknown	0.30 Microgram/Kilogram/Min	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132690	NON-EXPEDITED			US-ADVANZ PHARMA-202008007719			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132695	EXPEDITED (15-DAY)		OT	CA-ACCORD-194556		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Methotrexate			S	Subcutaneous			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Ramipril			S	Oral	1 Every 24 Hours		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Caffeine/Dihydrocodeine/Paracetamol			C	Unknown			Not Reported

	Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic	2 Every 1 Days	Not Reported
	Codeine/Paracetamol	C	Unknown		Not Reported
	Hydroxychloroquine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132701	NON-EXPEDITED			US-ADVANZ PHARMA-202007007665			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Fatigue; Hypersensitivity; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132793	NON-EXPEDITED			US-ADVANZ PHARMA-202008007693			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132831	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04442		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132833	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04499		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132836	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04501		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132839	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04498		47 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132843	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04500		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132845	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-064407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Topicort [Desoximetasone]	S	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18132974	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2020-04643		64 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk (A Five Day Course)		Lupin
	Cyclophosphamide;Fludarabine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133012	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04473		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Qd		Lupin
	Lopinavir			C	Unknown	800 Milligram, Qd		Not Reported
	Ritonavir			C	Unknown	200 Milligram, Qd		Not Reported
	Vitamin C [Ascorbic Acid]			C	Unknown	6 Gram, Qd		Not Reported
	Eculizumab			C	Unknown	900 Milligram (2 Doses)		Not Reported
	Enoxaparin			C	Subcutaneous	4000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133019	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04474		82 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Ceftriaxone			S	Intravenous (not	2 Gram, Qd		Lupin

				otherwise specified)		
	Lopinavir		C	Unknown	800 Milligram, Qd	Not Reported
	Ritonavir		C	Unknown	200 Milligram, Qd	Not Reported
	Vitamin C [Ascorbic Acid]		C	Unknown	6 Gram, Qd	Not Reported
	Eculizumab		C	Unknown	900 Milligram (2 Doses)	Not Reported
	Enoxaparin		C	Subcutaneous	4000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133020	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04450		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Qd		Lupin
	Lopinavir			C	Unknown	800 Milligram, Qd		Not Reported
	Ritonavir			C	Unknown	200 Milligram, Qd		Not Reported
	Vitamin C [Ascorbic Acid]			C	Unknown	6 Gram, Qd		Not Reported
	Eculizumab			C	Unknown	900 Milligram (2 Doses)		Not Reported
	Enoxaparin			C	Subcutaneous	4000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133022	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04475		53 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Qd		Lupin
	Lopinavir			C	Unknown	800 Milligram, Qd		Not Reported
	Ritonavir			C	Unknown	200 Milligram, Qd		Not Reported

	Vitamin C [Ascorbic Acid]	C	Unknown	6 Gram, Qd	Not Reported
	Eculizumab	C	Unknown	900 Milligram (2 Doses)	Not Reported
	Enoxaparin	C	Subcutaneous	4000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133094	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-04370		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid (On The First Day)		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (On Days 2-5)		Lupin
	Enoxaparin			C	Subcutaneous	40 Milligram, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Milligram, Bid (Dose Increased)		Not Reported
	Amoxicillin/Clavulanic Acid			C	Unknown	1 Dosage Form, Tid (1 G/200 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133107	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210551			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Disease Risk Factor; Drug Ineffective; Drug Intolerance; Infection; Inflammation; Injection Site Reaction; Interstitial Lung Disease; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Rash; Rheumatoid Arthritis; Swelling;	Plaquenil			S		Unk		Sanofi
	Cyclophosphamide			S		Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Phenytoin			S		Unk		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Therapeutic Product Effect Decreased	Imuran [Azathioprine]	S	Unk		Not Reported
	Simponi	S	Unk		Not Reported
	Azithromycin	C	Unk		Not Reported
	Celebrex	C	Unk, Unk		Not Reported
	Ezetrol	C	Unk		Not Reported
	Methotrexate	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133297	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-04315		74 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Favipiravir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133571	EXPEDITED (15-DAY)		HO	NVSC2020ES220682		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Renal Colic	Hydroxychloroquine			S	Oral	400 Mg, Q12h		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Q24h		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133595	EXPEDITED (15-DAY)		HO	CA-ACCORD-194522		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Gabapentin			S	Oral	2 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported

Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular	1 Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Every 4 Days	Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Fentanyl	S	Unknown		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days	Not Reported
	Enbrel	S	Unknown	1 Every 1 Weeks	Not Reported
	Ergocalciferol	C	Unknown	1 Every 1 Hours	Not Reported
	Aclasta	C			Not Reported
	Calcium Gluconate	C	Unknown	1 Every 1 Days	Not Reported
	Esomeprazole	C	Unknown	2 Every 1 Days	Not Reported
	Ferrous Gluconate	C	Unknown	1 Every 1 Days	Not Reported
	Lomotil	C	Unknown	1 Every 1 Days	Not Reported
	Nasonex	C	Unknown	2 Every 1 Days	Not Reported
	Nortriptyline	C	Oral	1 Every 1 Hours	Not Reported
	Omega-3 Fatty Acids	C	Unknown	2 Every 1 Days	Not Reported
	Oxycodone	C	Unknown		Not Reported
	Prednisone	C	Unknown	1 Every 1 Days	Not Reported
	Risedronic Acid	C			Not Reported
	Trazodone	C	Unknown	1 Every 1 Hours	Not Reported
	Tylenol	C	Oral	1 Every 1 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133596	EXPEDITED (15-DAY)		OT	CA-ACCORD-194262		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated;	Methotrexate			S	Oral			Accord
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Fosamax	S			Not Reported
	Folic Acid	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Certolizumab	S	Subcutaneous		Not Reported
	Arava	S			Not Reported
	Prednisone	S			Not Reported
	Actemra	S			Not Reported
	Hydroxychloroquine	S		1 Every 1 Days	Not Reported
	Folic Acid	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133801	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020299356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Transplacental	Unk		Pfizer
	Magnesium Sulfate			S	Transplacental	Unk		Pfizer
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	1 Dose Of Betamethasone 4 Hours Prior To Delivery		Not Reported
	Tocilizumab			S	Transplacental	Unk		Not Reported

Nitric Oxide	S	Transplacental	Inhaled		Not Reported
Remdesivir	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133873	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04404		52 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Darunavir;Ritonavir			C	Unknown	800/100 Mg A Day		Not Reported
	Low Molecular Weight Heparin			C	Unknown	4000 Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133875	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04531		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Lopinavir/Ritonavir			C	Oral	1 Dosage Form, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported
	Mycophenolic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133885	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04451		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin

	Hydroxychloroquine		S	Oral	200 Milligram, Bid (5-10 Days)	Lupin
	Lopinavir/Ritonavir		C	Oral	1 Dosage Form, Bid	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Tacrolimus		C	Unknown	Unk	Not Reported
	Mycophenolic Acid		C	Unknown	Unk	Not Reported
	Enalapril		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133904	EXPEDITED (15-DAY)		HO, OT	TR-ACCORD-194699			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported
	Favipiravir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133905	EXPEDITED (15-DAY)		HO, OT	TR-ACCORD-194700			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported
	Favipiravir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134107	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1070397		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Electrocardiogram Qt Prolonged; Hypotension; Off Label Use	Fentanyl			S	Intravenous (not otherwise specified)			Mylan
	Midazolam			S	Intravenous (not otherwise specified)	Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan

Hydroxychloroquine	S				Mylan
Amiodarone	S	Intravenous (not otherwise specified)	Unk		Mylan
Norepinephrine	S	Intravenous (not otherwise specified)	Unk		Mylan
Vancomycin	S	Intravenous (not otherwise specified)	Unk		Mylan
Vancomycin	S				Mylan
Doxycycline	S	Intravenous (not otherwise specified)	Unk		Mylan
Doxycycline	S				Mylan
Propofol	S	Intravenous (not otherwise specified)			Mylan
Cisatracurium	S	Intravenous (not otherwise specified)	Unk		Mylan
Cefepime	S	Intravenous (not otherwise specified)			Mylan
Oseltamivir	S	Unknown			Mylan
Oseltamivir	S				Mylan
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)			Mylan
Immune Globulin (Immunoglobulins Nos)	S				Mylan
Metformin	C	Unknown			Mylan
Insulin Lispro	C	Unknown			Mylan
Atenolol	C	Unknown			Mylan
Losartan	C	Unknown			Mylan
Heparin	C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134587	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04535		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S	Oral	400 Milligram, Bid	Lupin
	Hydroxychloroquine	S	Oral	200 Milligram, Bid (5-10 Days)	Lupin
	Prednisone	C	Unknown	Unk	Not Reported
	Tacrolimus	C	Unknown	Unk	Not Reported
	Everolimus	C	Unknown	Unk	Not Reported
	Enalapril	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134588	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04534		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Prednisone			C	Unknown	Unk		Not Reported
	Rapamycin			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134590	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04533		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Immunoglobulins Nos			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134591	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04536		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Lopinavir/Ritonavir			C	Oral	1 Dosage Form, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported
	Mycophenolic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134603	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04538		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Lopinavir/Ritonavir			C	Oral	1 Dosage Form, Bid		Not Reported
	Interferon Beta			C	Subcutaneous	250 Microgram Every 48 Hours		Not Reported
	Everolimus			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134604	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04532		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S	Oral	400 Milligram, Bid	Lupin
	Hydroxychloroquine	S	Oral	200 Milligram, Bid (5-10 Days)	Lupin
	Lopinavir/Ritonavir	C	Oral	1 Dosage Form, Bid	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tacrolimus	C	Unknown	Unk	Not Reported
	Mycophenolic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134605	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04537		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Lopinavir/Ritonavir			C	Oral	1 Dosage Form, Bid		Not Reported
	Everolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18134727	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811838			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Unknown	1000 Milligram Daily;		Not Reported
	Naprosyn [Naproxen]			S				Not Reported

	Orencia	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Vioxx	S	Unknown			Not Reported
	Leflunomide	C				Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135051	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811348			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135102	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811602		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling;	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Arava	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135104	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811600		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Methotrexate			S	Topical			Barr
	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydrochloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Naprosyn			S	Unknown	100 Milligram Daily;		Not Reported
	Naprosyn			S	Unknown	1000 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

	Xeljanz		S	Oral	5 Milligram Daily;	Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135136	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811604		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Other			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135137	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811617		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Treatment Failure; Weight	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Decreased	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Zostavax		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135293	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811831		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811372		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Azathioprine	C			Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811926			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135325	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812061		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135328	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812037			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135415	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811817			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135454	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811824		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported

	Xeljanz			S	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135482	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1811921			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135604	EXPEDITED (15-DAY)		HO	TR-AMNEAL PHARMACEUTICALS-2020-AMRX-02386		65 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135784	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000657			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy	Lasix			S	Unknown	20 Mg, Unk		Validus

Peripheral	Ramipril		S	Unknown	12.5 Mg, Qd	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Bisoprolol		S	Unknown	12.5 Mg, Qd	Not Reported
	Buprenorphine		S	Unknown	10 Mg, Qd	Not Reported
	Calcium Carbonate		S	Unknown	Unk	Not Reported
	Cyanocobalamin		S	Unknown	Unk	Not Reported
	Fish Oil		S	Unknown	Unk	Not Reported
	Furosemide W/Potassium Chloride		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil /00072603/		S	Unknown	Unk	Not Reported
	Pyridoxine Hydrochloride		S	Unknown	Unk	Not Reported
	Rivaroxaban		S	Unknown	15 Mg, Qd	Not Reported
	Pyridoxine Hydrochloride		S	Unknown	Unk	Not Reported
	Colecalciferol		S	Unknown	Unk	Not Reported
	Magnesium Gluconate		S	Unknown	Unk	Not Reported
	Magnesium Gluconate		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136209	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2020-022396		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Dexametasona			S	Intravenous (not otherwise specified)	(722a), 6 Mg C/24		Bausch And Lomb
	Dexametasona			S				Bausch And Lomb
	Hidroxicloroquina			S	Oral	(2143a), 400 Mg C/12 Hr Dc Y 200 Mg C/12 Maintenance		Not Reported
	Hidroxicloroquina			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram/24 Hr (501a)		Not Reported
	Ceftriaxona			S				Not Reported

	Remdesivir	S	Intravenous drip	(10009a), 100 Mg C/24h	Not Reported
	Remdesivir	S			Not Reported
	Azitromicina	S	Oral	(7019a) 500 Mg, Shock Dose And 250 Mg C/24 Hr Maintenance	Not Reported
	Azitromicina	S			Not Reported
	Midazolam	C		2256a	Not Reported
	Fentanilo	C		1543a	Not Reported
	Enoxaparina	C		2482a	Not Reported
	Cisatracurio	C		2738a	Not Reported
	Paracetamol	C		12a	Not Reported
	Omeprazol	C		2141a	Not Reported
	Enalapril	C		2142a	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136365	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022289		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136368	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate/Calvulanate Potassium			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136369	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022302		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain;	Penicillamine			S	Unknown	Not Specified		Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Ciclosporin			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Not Specified		Not Reported

Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Methotrexate	S	Unknown			Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Specified		Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Simponi	S	Unknown			Not Reported
	Amitriptyline Hydrochloride	C	Unknown			Not Reported
	Doxycycline	C	Unknown	Not Specified		Not Reported
	Prednisone	C	Unknown	Not Specified		Not Reported
	Sulfasalazine	C	Unknown	Not Specified		Not Reported
	Tobramycin	C	Unknown	Not Specified		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136373	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022297		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	5.0 Milligram 2 Every 1 Day	Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136374	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022288		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136375	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022290			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrochloroquine Sulfate Tab 200mg			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydrochloroquine			C	Unknown			Not Reported
	Lefulunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136416	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1812877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	C			Not Reported
	Enbrel	C			Not Reported
	Humira	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136514	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1813331			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136517	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-24380		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immunoglobulin (Immunoglobulin G Human)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Hexacetonide			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136541	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate	S	Unknown		Barr
	Hydroxychloroquine	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Amlodipine Besilate	C	Unknown	2.5 Milligram Daily;	Not Reported
	Gabapentin	C	Unknown	400 Milligram Daily;	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136544	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811355		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Investigation Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136567	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1811614			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Methotrexate			S	Subcutaneous			Barr

Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136570	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811366		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Contraindicated Product Administered; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab/Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Gabapentin			C	Unknown	1800 Milligram Daily;		Not Reported
	Reactine			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136574	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812033		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Mobicox	C	Unknown	15 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136580	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812035		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Methotrexate			S	Subcutaneous			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136659	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Intolerance; Eye Disorder; Lung Disorder; Macular Degeneration	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136689	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811639		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18137225	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022293			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18137249	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydrochloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	13228895	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832720		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling;	Actemra			S	Unknown	Therapy Duration: 1095.0 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 122.0 Days		Not Reported

Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel	S	Unknown	Therapy Duration: 365.0 Days	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 183.0 Days	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 183.0 Days	Not Reported
	Methotrexate Sodium	S	Unknown	Therapy Duraiton: 5 Years	Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Unknown	Therapy Duration: 548.0 Days	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Methotrexate	S	Endocervical		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Meloxicam	S	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	13251335	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006763		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	1.0 Df, Qd		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported
	Piroxicam			S	Unknown	Unk		Not Reported
	Apo-Mycophenolate			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	162 Milligram, Q.Wk.		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Q.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Intra-arterial	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Q.Wk.		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Plaquenil /00072602/	S	Oral	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	C	Unknown	7.5 Milligram		Not Reported
Piroxicam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	14801305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	15662825	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2569806-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Arava			S	Nasal			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S		Not Reported
	Methotrexate	S	Intra-articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	15739251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594156-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Oral	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Varilrix	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Diclofenac	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	15848951	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633323-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis; Sleep Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Parenteral	Not Reported
Otezla	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Salazopyrin	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sirukumab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ustekinumab	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Minocycline	S	Intramuscular	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	16774875	EXPEDITED (15-DAY)		OT	HK-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-218915			Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Sulfasalazine			S	Unknown	Unk		Sun
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	16884815	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418383		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Azathioprine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17030139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461478		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye;	Actemra			S	Unknown	Therapy Duration: 366.0		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 4		Not Reported

Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown	Months Therapy Duration: -59	Not Reported
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Mobicox	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil	C	Oral		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Pantoprazole Magnesium	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17148627	EXPEDITED (15-DAY)		OT	CA-ROCHE-2490224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Contraindication To Vaccination; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Therapy Duration 9.0 Months	Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Piroxicam	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Leflunomide	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17390831	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020054414		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Increased; Skin Cancer; Therapeutic Product Effect Decreased; Urinary Tract Infection	Xeljanz Xr	S	Oral	11 Mg, Daily		Pfizer
	Xeljanz Xr	S	Oral	11 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17449227	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552826		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17521749	EXPEDITED (15-DAY)		OT	CA-SA-2020SA060110			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Topicort			S	Cutaneous	Unk		Sanofi

Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra	S		Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Sanofi
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Sanofi
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17732774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587807		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17775772	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593600		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

Ineffective; Dyspnoea; Gait Disturbance; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Arava		S	Unknown	Not Reported
	Celecoxib		S	Oral	Not Reported
	Celecoxib		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Toradol		S	Unknown	Not Reported
	Tramadol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17810597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral	6.0 Years		Not Reported
	Leflunomide			S	Intramuscular			Not Reported
	Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown	Not Specified		Not Reported
	Naproxen			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	4.0 Years	Not Reported
	Orencia	S	Oral	6.0 Years	Not Reported
	Methotrexate	S	Intramuscular		Not Reported
	Methotrexate	S	Oral	6.O Years	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	Therapy Duration: 6.0 Years	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Ramipril	C	Unknown	Not Specified	Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Insulin	C	Unknown		Not Reported
	Lantus	C	Subcutaneous		Not Reported
	Lozide (Canada)	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Vitamin D [Ergocalciferol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17820863	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602973		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Rituximab			S	Intravenous (not			Not Reported

Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis				otherwise specified)	
	Sodium Aurothiomalate		S	Intramuscular	Not Reported
	Tacrolimus		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Azathioprine		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Mycophenolate Mofetil		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17832245	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605648		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17836199	EXPEDITED (15-DAY)		HO, OT	ES-VELOXIS PHARMACEUTICALS-2020VELES-000499		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; C-Reactive Protein Increased; Coronavirus Infection; Drug Interaction; Drug Level Increased; Gastrointestinal Disorder; Nephropathy Toxic; Off Label Use; Renal Failure	Envarsus			S	Unknown	Unk		Chiesi
	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Qd, 200/100mg (5 Day)		Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Mycophenolic Acid			S	Unknown	Unk (Dose Reduce)		Not Reported
	Mycophenolic Acid			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram (0.5 Day)		Not Reported
	Hydroxychloroquine			S	Oral	800 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram (0.5 Day)		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17863733	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611796		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Rituximab			S	Intravenous drip	3.0 Months		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	4.0 Months		Not Reported
	Enbrel			S	Subcutaneous	7.0 Months; 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	5.0 Months		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	5.0 Months		Not Reported
	Methotrexate			S	Unknown	4.0 Months		Not Reported
	Methotrexate			S	Oral	4.0 Months		Not Reported
	Orencia			S	Unknown	6.0 Months		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	5.0 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Advil			C				Not Reported
	Dequalinium Chloride			C				Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17903518	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-029227		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyshidrotic Eczema; Eczema; Off Label Use; Pruritus	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Enoxaparin Sodium			S	Subcutaneous	1 Dosage Form, Once A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Plaquenil			S	Oral	2 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17920297	EXPEDITED (15-DAY)		OT	CA-ACCORD-185747		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Accord
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Unknown	1 Every 1 Days	Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S			Not Reported
Sulfathalidine	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Golimumab	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Reactine (Cetirizine)	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Oral	Frequency: 1 Every 1 Days	Accord
Sulfasalazine	S	Oral	2 Every 1 Days	Not Reported
Folic Acid	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	17954674	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-20926			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported

	Triamcinolone	S	Other	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18010940	EXPEDITED (15-DAY)		HO	NVSC2020IT187427		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyshidrotic Eczema; Eczema; Off Label Use; Pruritus	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Plaquenil			S	Oral	2 Df, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	1 Df, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Qd (200 Mg/50 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18064107	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-036517		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Aurobindo
	Voriconazole			S	Intravenous (not otherwise specified)	600 Milligram, Two Times A Day		Aurobindo
	Hydroxychloroquine			S	Oral	200 Milligram, 3 Times A Day		Not Reported
	Hydroxychloroquine			S	Unknown	3600 Milligram		Not Reported
	Piperacillin;Tazobactam			S	Intravenous (not otherwise specified)	4 Gram, Four Times/Day		Not Reported
	Enoxaparin			C	Subcutaneous	6000 International Unit, Two Times A Day		Not Reported
	Cefepime			C	Intravenous (not	2 Milligram, Two Times A		Not Reported

otherwise specified) Day

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18085179	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1067895		79 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd(500mg/Day)		Mylan
	Plaquinol			S	Oral	400 Milligram, Qd(400mg 12/12h Em D0)		Mylan
	Acetylsalicylic Acid			C	Oral	150 Milligram, Qd		Mylan
	Levofloxacin			C	Intravenous (not otherwise specified)	750 Milligram, Total		Mylan
	Ipratropium Bromide			C	Respiratory (inhalation)	2 Dosage Form, Qd		Mylan
	Haloperidol-Ratiopharm			C	Intramuscular	5 Milligram, Prn		Mylan
	Paracetamol			C	Intravenous (not otherwise specified)	1000 Milligram, Prn		Mylan
	Ceftriaxone			C	Intravenous (not otherwise specified)	4000 Milligram, Qd		Mylan
	Omeprazole			C	Oral	20 Milligram, Qd		Mylan
	Sodium Chloride			C	Intravenous (not otherwise specified)	500 Milliliter, Qd(2000 Ml Em D0)		Mylan
	Salbutamol			C	Respiratory (inhalation)	2 Dosage Form, Qd		Mylan
	Quetiapina /01270901/			C	Oral	50 Milligram, Qd (Ao Pequeno-Almoço)		Mylan
	Rivastigmine			C	Transdermal	Unk		Mylan
	Chlorpromazine			C		Unk, Em Sos		Mylan
	Memantine			C	Oral	20 Milligram, Qd Ao Pequeno-Almoço		Mylan
	Simvastatin			C	Oral	20 Milligram Ao Jantar		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18089290	EXPEDITED (15-DAY)		OT	NVSC2020PT210583		65 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Plaquinol			S	Oral	400mg De 12/12h Em D0 E Depois 200mg 12/12h		Not Reported
	Quetiapine			C	Oral	Unk		Not Reported
	Esomeprazole			C	Oral	40 Mg, Qd		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	4 Inalações 6/6h		Not Reported
	Trazodone			C	Oral	50 Mg, Qd		Not Reported
	Levothyroxine Sodium			C	Oral	50 Ug, Qd		Not Reported
	Piperacillin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Clonidine			C	Oral	0.15 Mg, Qd		Not Reported
	Salbutamol			C	Respiratory (inhalation)	6 Inalações 4/4h		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	20 Mg, Qd		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, Qd		Not Reported
	Escitalopram			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18122790	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1046010		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pneumonia Bacterial; Staphylococcal Bacteraemia	Spiramycin			S	Other	6 Mu, Qd		Not Reported
	Cefotaxime			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported
	Cefotaxime			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported

Vancomycin	S	Intravenous (not otherwise specified)	2 G, Qd		Mylan
Hydroxychloroquine Sulfate	S	Other	400 Mg, Qd		Mylan
Hydroxychloroquine Sulfate	S	Other	600 Milligram, Qd		Mylan
Hydroxychloroquine Sulfate	S	Other	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137248	EXPEDITED (15-DAY)		LT, OT	ES-HETERO-HET2020ES00891		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Clonus; Delirium; Depressed Level Of Consciousness; Drug Interaction; Encephalopathy; Hyperhidrosis; Hyperreflexia; Hypertension; Myoclonus; Off Label Use; Serotonin Syndrome; Speech Sound Disorder; Tachycardia; Urinary Retention	Duloxetine			S	Unknown	120 Mg, Qd		Hetero
	Duloxetine			S				Hetero
	Lithium			S	Unknown	800 Mg, Qd		Not Reported
	Haloperidol			S	Unknown	1 Mg, Bid		Not Reported
	Lopinavir/Ritonavir			S	Unknown	400 Mg/ 100 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137578	EXPEDITED (15-DAY)		OT	CA-ROCHE-2655617			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Topicort (Canada)	S	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137779	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04504		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137782	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04507		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137784	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04506		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137791	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04467		49 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Oseltamivir			S	Unknown	75 Milligram, Bid		Lupin
	Ribavirin			S	Unknown	400 Milligram, Bid		Not Reported
	Naproxen			C	Unknown	500 Milligram, Bid		Not Reported
	Levofloxacin			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137797	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04509		60 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137798	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04508		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137800	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04510		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137802	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04503		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137803	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04502		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137805	EXPEDITED (15-DAY)		OT	GR-LUPIN PHARMACEUTICALS INC.-2020-04347		82 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Impairment; Respiratory Failure	Hydroxychloroquine			S	Unknown	200 Milligram, Tid		Lupin
	Ceftriaxone			S	Unknown	2 Gram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18137810	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04505		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138151	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04511		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Darunavir			S	Unknown	Unk		Not Reported
	Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138152	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04514		69 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Darunavir			S	Unknown	Unk		Not Reported
	Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138156	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04512		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138157	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04515		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

	Darunavir		S	Unknown	Unk	Not Reported
	Ritonavir		C	Unknown	Unk	Not Reported
	Methylprednisolone		C	Unknown	16 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138163	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04513		50 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Darunavir			S	Unknown	Unk		Not Reported
	Ritonavir			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	16 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2655314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138215	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04526		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138246	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04621		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Cobicistat;Darunavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138251	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-04612			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pneumonia; Premature Baby	Oseltamivir			S	Transplacental	Unk		Lupin
	Methylprednisolone			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Ribavirin			S	Transplacental	Unk		Not Reported
	Arbidol			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138303	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04330		42 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Stevens-Johnson Syndrome	Hydroxychloroquine		S	Unknown	200 Milligram, Bid	Lupin
	Acetaminophen		C	Unknown	500 Milligram, Qid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138934	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04470		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Atorvastatin Calcium			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Aspirin (E.C.)			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138936	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04542		67 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Lopinavir/Ritonavir			C	Oral	1 Dosage Form, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Cyclosporine			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138939	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04543		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine		S	Oral	400 Milligram, Bid	Lupin
	Hydroxychloroquine		S	Oral	200 Milligram, Bid (5-10 Days)	Lupin
	Lopinavir/Ritonavir		C	Oral	1 Dosage Form, Bid	Not Reported
	Interferon Beta		C	Subcutaneous	250 Microgram, Every 48 Hours	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Cyclosporine		C	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		C	Unknown	Unk	Not Reported
	Enalapril		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138941	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04541		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Prednisone			C	Unknown	Unk		Not Reported
	Cyclosporine			C	Unknown	Unk		Not Reported
	Mycophenolic Acid			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138943	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04544		38 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Mycophenolic Acid			C	Unknown	Unk		Not Reported

	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138948	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04539		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Interferon Beta			C	Subcutaneous	250 Microgram, Every 48 Hours		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported
	Everolimus			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18138949	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04540		76 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (5-10 Days)		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139335	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-2029612US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract;	Memantine Hcl - Bp			S	Unknown			Allergan

Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Product Use In Unapproved Indication; Purpura; Skin Disorder; Weight Increased	Amitriptyline	S		Not Reported
	Amlodipine Besilate	S		Not Reported
	Anakinra	S		Not Reported
	Apremilast	S		Not Reported
	Bumetanide	S		Not Reported
	Capsaicin	S		Not Reported
	Cimetidine	S		Not Reported
	Clonidine	S		Not Reported
	Diltiazem	S		Not Reported
	Etanercept	S		Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ibudilast	S		Not Reported
	Ketamine	S		Not Reported
	Lidocaine	S		Not Reported
	Lithium Carbonate	S		Not Reported
	Magnesium	S		Not Reported
	Metprolol	S		Not Reported
	Montelukast	S		Not Reported
	Mycophenolate Mofetil	S		Not Reported
	N-Acetylcysteine	S		Not Reported
	Palmidrol	S		Not Reported
	Pentoxifylline	S		Not Reported
	Spironolactone	S		Not Reported
	Vitamin B 2	S		Not Reported
	Vitamin C	S		Not Reported
	Prednisone	S	5 Mg, Qd	Not Reported
	Prednisone	S	85 Mg, Qd	Not Reported
	Prednisone	S	95 Mg, Qd	Not Reported
	Naltrexone Hydrochloride	S	4.5 Mg, Qd	Not Reported
	Calcitonin	C		Not Reported
	Ezetimibe	C		Not Reported
	Trazodone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139340	EXPEDITED (15-DAY)		HO	CA-ROCHE-2655619		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug	Mycophenolate Mofetil			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Mycophenolate Mofetil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139346	EXPEDITED (15-DAY)		OT	NVSC2020US206386			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Septic Shock	Blinded Ascorbic Acid			S	Oral	Code Not Broken		Novartis
	Blinded Hydroxychloroquine Sulfate			S	Oral	Code Not Broken		Novartis
	Blinded Hydroxychloroquine Sulfate			S	Oral	Code Not Broken		Novartis
	Blinded No Treatment Received			S	Oral	Code Not Broken		Novartis
	Blinded Ascorbic Acid			S				Novartis
	Blinded Hydroxychloroquine Sulfate			S				Novartis
	Blinded Hydroxychloroquine Sulfate			S				Novartis
	Blinded No Treatment Received			S				Novartis
	Acetaminophen			C	Unknown	Unk		Not Reported
	Hydrocortisone			C	Unknown	Unk		Not Reported
	Sirolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139944	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812056		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139946	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1811991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	12.5 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140041	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04559		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Tocilizumab			C	Unknown	2 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140057	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-04327		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Ceftriaxone			S	Unknown	Unk		Lupin
	Ceftriaxone			S				Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Azithromycin			S				Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Heparin			C	Subcutaneous	5000 International Unit, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140082	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812048		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported

Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Syringe Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Mefenamic Acid		C			Not Reported
	Prednisone		C			Not Reported
	Tylenol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140180	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-25246			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported

	Sulfasalazine		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140498	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020306057			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140519	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020306064			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	7.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140721	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020305998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Sulfasalazine			S	Unknown	Unk		Pfizer

Increased; Drug Ineffective; Drug Intolerance; Orthostatic Hypotension; Palmoplantar Pustulosis; Presyncope; Rash; Red Blood Cell Sedimentation Rate Increased; Retinopathy	Methotrexate Sodium	S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium	S	Oral	Unk		Pfizer
	Hydroxychloroquine Sulphate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18141315	EXPEDITED (15-DAY)		OT	NVSC2020US222131		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	400 Mg(Only One Dose)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142173	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022286			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142181	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-022287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142766	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812043		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142768	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142775	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812855		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown	1.2 Ml, 1 Every 1 Week		Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142783	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1812861		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Musculoskeletal Disorder	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142788	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1813285		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142819	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812881			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142863	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1813329		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142865	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1813281		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142876	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Hydrocortisone Valerate			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Lyderm	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142882	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1813283		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142883	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812016		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate)	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142885	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	50 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142887	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812783		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142907	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142930	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1813274		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

					otherwise specified)					
	Rituximab			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142931	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812887			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenacz			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	20 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142932	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1812857		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142942	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1812871			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Zostavax	S	Intravenous (not otherwise specified)			Not Reported
Cortisone Acetate	C	Subcutaneous			Not Reported
Desoximetasone	C	Oral			Not Reported
Diclofenac	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
Xeljanz	C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18143739	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2655342			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Concentrate For Solution For Infusion		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported

	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18143782	EXPEDITED (15-DAY)		OT	CA-ROCHE-2655479			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Leukopenia	Actemra			S	Unknown			Not Reported
	Codeine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18143816	EXPEDITED (15-DAY)		OT	TH-ROCHE-2655978		47 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative;	Alecensa			S	Unknown			Not Reported

Rheumatoid Arthritis; Therapy Partial Responder	Alecensa		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown	5 Tabs X 2.5mg Per Day	Not Reported
	Cyclosporin A		S	Unknown		Not Reported
	Etanercept		S	Subcutaneous		Not Reported
	Prednisolone		S	Unknown		Not Reported
	Enoxaparin		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	14241947	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021741		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	14467684	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Doxycycline			S				Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Q.M.T.		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Unknown	5 Milligram		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	15337632	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019421		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema;	Leflunomide			S	Unknown	5 Mg, Therapy Duration 365		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Milligram		Apotex
	Apo-Leflunomide			S	Unknown	5 Milligram		Apotex

Gastrointestinal Disorder; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Tuberculin Test Positive; Urinary Tract Infection	Hydroxychloroquine	S	Unknown	5 Mg, Unk	Apotex
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Apotex
	Hydroxychloroquine	S	Oral	5 Milligram	Apotex
	Cimzia	S	Subcutaneous	200 Mg, Cyclical	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Methotrexate	S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Q.Wk.	Not Reported
	Orencia	S	Unknown	750 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	50 Mg, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	15574827	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018445878		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Product Use In Unapproved Indication; Synovitis	Sulfasalazine	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Etanercept	S		Unk	Pfizer
	Infliximab Hospira	S		Unk	Pfizer
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Minocycline	S		Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported

Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported
Golimumab	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Ustekinumab	S	Subcutaneous	Unk		Not Reported
Dilaudid	C		Unk		Not Reported
Dilaudid	C		Unk		Not Reported
Dilaudid	C		Unk		Not Reported
Wellbutrin	C		Unk		Not Reported
Wellbutrin	C		Unk		Not Reported
Wellbutrin	C		Unk		Not Reported
Bupropion Hydrochloride	C		Unk		Not Reported
Hydromorphone Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	15712507	EXPEDITED (15-DAY)		OT	AU-ROCHE-2225758			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Neuropathy Peripheral; Vision Blurred	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Lovan			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	16071269	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis;	Infliximab			S	Unknown	Unknown		Not Reported

Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown, Subcutaneous Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	16085271	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Oral	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Subcutaneous	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous (Single Use Pre-Filled Syringe)	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S			Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	16438993	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2017-04887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia; Off Label Use	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Apo-Leflunomide	S	Unknown			Not Reported
Humira	S	Subcutaneous	Unknown		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S				Not Reported
Orencia	S	Unknown	Unknown		Not Reported
Orencia	S				Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported
Pregabalin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	16468449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-058879		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Laryngeal Disorder; Nausea; Pain; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Arava			S	Oral	20 Milligram, Qwk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	400 Milligram, Qwk		Not Reported

Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, 2 Every 1 Days	Not Reported
Imuran [Azathioprine]	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Unknown	250 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Q8wk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Piroxicam	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17575971	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP008932		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex

Hydroxychloroquine	S	Oral	200 Mg, Bid	Apotex
Apo-Leflunomide	S	Unknown	10 Mg, Qd	Apotex
Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
Apo-Leflunomide	S	Unknown	Unk, Unknown	Apotex
Actemra	S	Unknown	650 Mg, Q.M.T.	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12.5 Dosage Form	Not Reported
Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Q.O.Wk.	Not Reported
Gold	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	25 Milligram	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	750 Mg, Q.M.T.	Not Reported
Plaquenil	S	Oral	200 Mg, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk (1 Every 6 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Unk, Cyclical	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported

Sodium Aurothiomalate	S	Intramuscular	Unk		Not Reported
Arava	S	Oral	10 Mg, Unk		Not Reported
Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	1000 Mg, Unk		Not Reported
Sulfasalazine	S	Subcutaneous	Unk		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Actemra	C	Unknown	Unk		Not Reported
Arava	C	Oral	10 Mg, Unk		Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported
Loperamide	C	Unknown	Unk		Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.		Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	40 Mg, Unk		Not Reported
Prednisone	C	Unknown	250 Mg, Unk		Not Reported
Simponi	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17688868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Sanofi
	Chloroquine Phosphate			S	Unknown			Sanofi
	Myochrysine			S	Unknown			Not Reported

	Humira	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17767661	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2020180079			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17848194	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3205448-00		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Xarelto			C				Not Reported
	Prednisone			C		Qd, Tapering		Not Reported
	Hydrocortisone			C				Not Reported
	Tylenol Arthritis			C				Not Reported
	Calcium Carbonate With D3			C				Not Reported
	Pantoloc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17859082	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606894			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17859463	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202005006112			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Delftia Acidovorans Infection; Device Related Sepsis; Enterococcal Infection; Incorrect Route Of Product Administration; Off Label Use; Pneumonia Bacterial; Pseudomonas Infection; Septic Shock; Septic Shock; Staphylococcal Infection	Hydroxychloroquine			S	Intravenous (not otherwise specified)	600 Mg, Qd		Concordia
	Kevzara			S	Intravenous (not otherwise specified)	400 Mg, Qd, Injectable Syringe		Not Reported
	Zithromax			S	Oral	250 Mg, Coated Tablet		Not Reported
	Zithromax			S	Oral	250 Mg		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Cloxacilline			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Sevoflurane			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Amlor			C		Unk		Not Reported
	Tercian			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Amikacine			C		Unk		Not Reported
	Caspofungine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17893666	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-028677		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Amiodarone			S	Unknown	Unk		Aurobindo
	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Bisoprolol			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Sarilumab			S	Subcutaneous	400 Milligram, , 1x		Not Reported
	Spiramycin			S	Unknown	Unk		Not Reported
	Hydroxyzine			C	Unknown	Unk		Not Reported
	Monoprost			C	Unknown	Unk		Not Reported
	Gabapentine			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Eplerenone			C	Unknown	Unk		Not Reported
	Tamsulosine			C	Unknown	Unk		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Oxazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	17902484	EXPEDITED (15-DAY)		HO	IT-SA-2020SA154460			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyshidrotic Eczema; Eczema; Off Label Use; Pruritus	Plaquenil			S	Oral	2 Df, Qd		Sanofi
	Plaquenil			S				Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	1 Df, Qd		Sanofi
	Lopinavir/Ritonavir			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18005754	EXPEDITED (15-DAY)		OT	NVSC2020JO194148			Female	JOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Maternal Dose:400 Mg Twice Daily For A Total Of 9 Days		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18063152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1804295		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Oral	1 Dosage Forms Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

	Acetaminophen;Oxycdone Hydrochloride	C			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	1000 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	1000 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen	C	Oral		Not Reported
	Naproxen	C	Oral	1000 Milligram Daily;	Not Reported
	Oxycodone Hydrochloride	C			Not Reported
	Rosuvastatin Calcium	C	Oral		Not Reported
	Rosuvastatin Calcium	C	Oral		Not Reported
	Valtrex	C	Oral	2000 Milligram Daily;	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18076389	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1805030		86 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19 Treatment; Nausea	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported
	Plaquinol			S	Oral	400mg 12 / 12h In D0 And Then 200mg 12 / 12h		Not Reported
	Potassium Chloride			C	Intravenous (not otherwise specified)	40 Milliequivalents		Not Reported
	Escitalopram			C	Oral	10 Mg		Not Reported
	Metoclopramide			C	Intravenous (not otherwise specified)	Sos Up To A Maximum Of 30 Mg / Day		Not Reported
	Enoxaparin Sodium			C		40 Mg		Not Reported
	Bromazepam			C	Oral	Sos Up To 1.5 Mg / Day		Not Reported
	Amlodipine			C	Oral	5 Mg		Not Reported
	Pantoprazole			C	Oral	20 Mg		Not Reported

Furosemide	C	Oral	40 Mg	Not Reported
Losartan + Hidroclorotiazida	C	Oral	1 Dosage Forms	Not Reported
Paracetamol	C	Intravenous (not otherwise specified)	Sos	Not Reported
Piperacilina + Tazobactam	C	Intravenous (not otherwise specified)	18000 Mg	Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg	Not Reported
Potassium Chloride	C	Oral	1200 Mg	Not Reported
Gabapentin	C	Oral	200 Mg	Not Reported
Azithromycin	C	Intravenous (not otherwise specified)	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18080092	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202007007353			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Oseltamivir			C		Unk		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin Lispro			C				Not Reported
	Metformin			C				Not Reported
	Atenolol			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported

	Midazolam	C		Unk	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Doxycycline	C		Unk	Not Reported
	Immunoglobulin I.V	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Heparin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18104003	NON-EXPEDITED			US-TEVA-2020-US-1811170			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine (Prasco)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18110366	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1810021		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Heparin-Induced Thrombocytopenia; Heparin-Induced Thrombocytopenia; Off Label Use; Pulmonary Embolism	Hydroxychloroquine			S	Unknown			Teva
	Unfractionated Heparin			S	Subcutaneous	5000 Units		Not Reported
	Unfractionated Heparin			S	Unknown	18 Units/Kg; Infusion		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Nitric Oxide			S	Other			Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Azithromycin			C	Unknown			Not Reported
	Remdesivir			C	Unknown			Not Reported
	Norepinephrine			C	Unknown			Not Reported
	Vasopressin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18110473	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1810027		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heparin-Induced Thrombocytopenia; Heparin-Induced Thrombocytopenia; Off Label Use; Skin Necrosis	Hydroxychloroquine			S	Unknown			Teva
	Unfractionated Heparin			S	Other			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Azithromycin			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Cisatracurium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18122221	EXPEDITED (15-DAY)		DE	PT-TEVA-2020-PT-1809486		89 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis; Covid-19 Treatment; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Milligram Daily; Additional Drug Information: Pneumonia At Sars-Cov 2,		Not Reported
	Plaquinol			S	Oral	400mg Of 12 / 12h In D0 And Then 200mg Of 12 / 12h		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)			Not Reported
	Amiodarone			C	Intravenous (not otherwise specified)			Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)			Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)			Not Reported
	Meropenem			C	Intravenous (not			Not Reported

		otherwise specified)	
Enoxaparin Sodium	C	Subcutaneous	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	Not Reported
Lactitol	C	Oral	Not Reported
Calcium Gluconate	C	Intravenous (not otherwise specified)	Not Reported
Glucose	C	Intravenous (not otherwise specified)	Not Reported
Human Serum Albumin	C	Intravenous (not otherwise specified)	Not Reported
Oxazepam	C	Oral	Not Reported
Potassium Dihydrogen Phosphate	C	Intravenous (not otherwise specified)	Not Reported
Esomeprazole	C	Intravenous (not otherwise specified)	Not Reported
Paracetamol	C	Intravenous (not otherwise specified)	Not Reported
Amoxicilina + Acido Clavulanico	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18124774	NON-EXPEDITED			US-PFIZER INC-2020294717		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Drug Ineffective; Drug Intolerance	Enbrel			S		50 Mg		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

Leflunomide	S	Unk	Not Reported
Rinvoq	S	Unk	Not Reported
Simponi	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18129527	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202006006894			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jugular Vein Thrombosis; Off Label Use; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd		Concordia
Bacterial; Staphylococcal Bacteraemia;	Kevzara			S	Intravenous (not otherwise specified)	400 Mg, Single Dose For 1 Hour		Not Reported
Staphylococcal Bacteraemia; Staphylococcal Infection; Thrombosis	Kevzara			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Zithromax			S	Oral	500 Mg, Qd		Not Reported
	Zithromax			S	Oral	250 Mg, Qd		Not Reported
	Diprivan			C		Unk		Not Reported
	Tracrium			C		Unk		Not Reported
	Hypnovel			C		Unk		Not Reported
	Sufenta			C				Not Reported
	Noradrenaline			C				Not Reported
	Lantus			C				Not Reported
	Novorapid			C				Not Reported
	Heparine			C		Unk		Not Reported
	Umuline			C				Not Reported
	Lansoprazole			C				Not Reported
	Tazocilline			C		Unk		Not Reported
	Amikacin			C		Unk		Not Reported
	Lasilix			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18141923	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Other			Not Reported
	Methylprednisolone Acetate			C	Other			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown	Dosage Form: Not Specified		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18141980	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-04		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Mobicox	S	Unknown		Boehringer Ingelheim
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Methylprednisolone Acetate	C	Other		Not Reported
	Methylprednisolone Acetate	C	Other		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18142185	EXPEDITED (15-DAY)		DS	FR-ADVANZ PHARMA-202007007658			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypotension; Impaired Driving Ability; Pigmentation Disorder; Somnolence	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Tablets At Once In The Morning At Breakfast		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18142195	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202008007723			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nasal Neoplasm; Treatment Noncompliance	Hydroxychloroquine		S		Unk	Concordia
	Xeljanz Xr		S	Oral	11 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18142212	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007683			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Therapeutic Product Effect Incomplete; Ulcer	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Oxycodone			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18142544	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-04			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise;	Mobicox			S	Unknown	Dosage Form: Not Specified		Boehringer Ingelheim
	Actemra			S	Subcutaneous	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported

Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Depo-Medrol	C	Unknown	Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Humira	C	Unknown	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18142964	EXPEDITED (15-DAY)		HO, LT, OT	IR-ADVANZ PHARMA-MAPI_00011488			Unknown	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Magnetic Resonance Imaging Brain Abnormal; Posterior Reversible Encephalopathy Syndrome	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Cyclophosphamide			S	Unknown	500 Mg (Pulse Ttherapy)		Not Reported
	Cyclophosphamide			S	Unknown	500 Mg (Second Pulse Therapy) 2 Weeks Later		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Prednisolone			S	Unknown	70 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2656391		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Apremilast			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Penicillin Nos	C	Unknown	Not Reported
Infliximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143140	EXPEDITED (15-DAY)		HO, LT	RO-AUROBINDO-AUR-APL-2020-038675		72 YR	Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Transaminases Increased	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	8 Milligram/Kilogram, Single Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143278	EXPEDITED (15-DAY)		OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-256977		35 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	Sars-Cov-2		Sun

	Meropenem	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	800 Mg/Administration, 3 Administrations	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143656	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-04		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Mobicox			S	Unknown			Boehringer Ingelheim
	Meloxicam			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form Of Administration-Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	Form Of Administration-Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143854	EXPEDITED (15-DAY)		OT	CA-ACCORD-195007		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Dosage Form: Solution Subcutaneous, Single-Use Prefilled Syringe		Not Reported
	Codeine			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Dilaudid			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143893	EXPEDITED (15-DAY)		OT	PH-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-217717		24 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Methylprednisolone			S	Unknown	One Gram For Three Consecutive Days		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Prednisone			S	Oral	60 Milligram, Daily		Mutual
	Hydrocortisone			S	Intravenous (not	100 Mg		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143964	EXPEDITED (15-DAY)		HO	DE-TEVA-2020-DE-1812737		50 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19; Covid-19 Pneumonia; Intentional Product Misuse; Off Label Use	Prednisolone			S	Unknown	At Doses Of 20-30 Mg/Day		Actavis
	Hydroxychloroquine			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18143980	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-195013		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Methotrexate			S				Accord
	Isoniazid/Isoniazid Calcium Pyruvinate/Isoniazid Sodium Glucuronate			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Paracetamol			C	Oral			Not Reported
	Azathioprine			C				Not Reported
	Diphenhydramine			C				Not Reported
	Folic Acid			C				Not Reported
	Glyburide			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Pariet			C				Not Reported
	Ramipril			C				Not Reported
	Synthroid			C				Not Reported
	Linagliptin			C				Not Reported

	Pyridoxine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144591	EXPEDITED (15-DAY)		OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-256984		58 YR	Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144593	EXPEDITED (15-DAY)		OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-256985		72 YR	Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Tocilizumab			S	Unknown	8 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144961	EXPEDITED (15-DAY)		OT	CA-ACCORD-195045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate			S		1 Every 1 Weeks		Accord
	Prednisone			S				Not Reported
	Cosentyx			S		1 Every 1 Months		Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Paracetamol			C				Not Reported
	Cymbalta			C	Oral	1 Every 1 Days		Not Reported

	Naproxen/Esomeprazole	C	Oral		Not Reported
	Leflunomide	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144963	EXPEDITED (15-DAY)		OT	CA-ACCORD-195318			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144967	EXPEDITED (15-DAY)		OT	CA-ACCORD-195321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone			C				Not Reported

Pectinate/Oxycodone Terephthalate

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144972	EXPEDITED (15-DAY)		OT	CA-ACCORD-195037		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144974	EXPEDITED (15-DAY)		OT	CA-ACCORD-195003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144987	EXPEDITED (15-DAY)		DS, HO	CA-ACCORD-195005			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	1 Every 24 Hours		Not Reported
	Enbrel			S	Subcutaneous	4 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 24 Hours		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Prednisone			S	Oral	2 Every 1 Days		Not Reported
	Sulfasalazine			S	Oral	1 Every 24 Hours		Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144988	EXPEDITED (15-DAY)		OT	CA-ACCORD-195006		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown	Not Specified		Not Reported

Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Sunconjunctival	Subconjunctival	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine (Cetirizine)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cortisone	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144989	EXPEDITED (15-DAY)		OT	CA-ACCORD-195008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown	Not Specified		Not Reported
	Rituximab			S	Unknown			Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144990	EXPEDITED (15-DAY)		OT	CA-ACCORD-195323		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Endocervical			Not Reported

Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral			Not Reported
Xeljanz	C	Oral	2 Every 1 Days		Not Reported
Hydroxychloroquine	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate	S	Oral			Not Reported
Neoral	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144999	EXPEDITED (15-DAY)		OT	CA-ACCORD-195313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown	1 Every 1 Days		Not Reported
	Xeljanz			C				Not Reported
	Meloxicam			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145014	EXPEDITED (15-DAY)		OT	CA-ACCORD-195032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown	1 Every 1 Days		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		S	Oral	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145045	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020309364		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hepatic Fibrosis; Joint Dislocation; Non-Alcoholic Steatohepatitis	Methotrexate Sodium			S	Oral	15 Mg Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg Weekly		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Sulfasalazine			S	Oral	500 Mg		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		400 Mg		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Once Daily X M		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral	200 Mg		Not Reported
	Folic Acid			C	Oral	5 Mg, 1x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Methotrexate Pharmascience			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145755	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015835		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event;	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex

Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Cefazolin		S	Intramuscular	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	200 Milligram, Bid	Not Reported
	Naproxen		C	Unknown	500 Mg, Bid	Not Reported
	Viread		C	Unknown		Not Reported
	Arava		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145794	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1070624		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Norepinephrine			S	Unknown	Unk		Mylan
	Norepinephrine			S				Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Azithromycin			S	Unknown	Unk		Mylan
	Vasopressin			S	Unknown	Unk		Mylan
	Vasopressin			S				Mylan
	Lisinopril			C	Unknown	Unk		Mylan
	Methylprednisolone			C	Unknown	Unk		Mylan
	Heparin			C	Unknown	Therapeutic Dose		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145821	EXPEDITED (15-DAY)		OT	CA-ACCORD-195322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146293	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070272		81 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiopulmonary Failure; Off Label Use	Caspofungin			S		Unk		Mylan
	Piperacillin			S		Unk		Not Reported
	Tazobactam			S		Unk		Mylan
	Maraviroc			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146296	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070284		82 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intestinal Haemorrhage; Off Label Use	Piperacillin		S	Unk	Not Reported
	Caspofungin		S	Unk	Mylan
	Hydroxychloroquine		S	Unk	Mylan
	Tazobactam		S	Unk	Mylan
	Maraviroc		S	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146297	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070280		79 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Caspofungin			S		Unk		Mylan
	Piperacillin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Maraviroc			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146298	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070275		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiopulmonary Failure; Off Label Use	Piperacillin			S		Unk		Not Reported
	Caspofungin			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Maraviroc			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146310	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070266		78 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Respiratory Failure	Caspofungin		S	Unk	Mylan
	Piperacillin		S	Unk	Not Reported
	Hydroxychloroquine		S	Unk	Mylan
	Tazobactam		S	Unk	Mylan
	Maraviroc		S	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146311	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070260		72 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Aciclovir			S		Unk		Mylan
	Caspofungin			S		Unk		Mylan
	Piperacillin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Maraviroc			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146312	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070263		76 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiopulmonary Failure; Off Label Use	Aciclovir			S		Unk		Mylan
	Caspofungin			S		Unk		Mylan
	Piperacillin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Maraviroc			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146314	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070278		84 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Piperacillin			S		Unk		Not Reported
	Caspofungin			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Maraviroc			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146315	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070291		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Piperacillin			S		Unk		Not Reported
	Caspofungin			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Maraviroc			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146316	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070288		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Caspofungin			S		Unk		Mylan
	Piperacillin			S		Unk		Not Reported
	Maraviroc			S		Unk		Mylan
	Golimumab			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146385	NON-EXPEDITED			US-ADVANZ PHARMA-202007007553			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Musculoskeletal Stiffness; Pain; Therapy Cessation	Hydroxychloroquine			S		Unk		Concordia
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146654	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1813309		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Haemorrhage Subcutaneous; Product Substitution Issue	Hydroxychloroquine Sulfate Teva			S	Unknown			Teva
	Hydroxychloroquine Sulfate Teva			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146761	EXPEDITED (15-DAY)		OT	CA-ROCHE-2656274		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146891	NON-EXPEDITED			US-SA-2020SA206083			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Mouth Ulceration; Treatment Failure; Unevaluable Event	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18147259	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25241			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone Acetonide		S	Intra-articular	Unknown, Suspension Intra-Articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149191	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25250			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Unknown, Suspension Intra-Articular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149196	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Triamcinolone Acetonide			S	Unknown	Unknown, Suspension Intra- Articular		Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Triamcinolone Acetonide			S				Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	10187077	EXPEDITED (15-DAY)		OT	CA-ROCHE-1301050		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Arthralgia; Back Pain; Blood Pressure Fluctuation; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Chest Pain; Cough; Depression; Device Breakage; Dry Throat; Erythema; Fatigue; Fatigue; Feeling Hot; Gastritis; Headache; Heart Rate Decreased; Heart Rate Decreased; Hot Flush; Infection; Infusion Related Reaction; Infusion Related Reaction; Intentional Product Use Issue; Labyrinthitis; Migraine; Musculoskeletal Chest Pain; Nasopharyngitis; Neuralgia; Off Label Use; Oxygen Saturation Decreased; Pain In Extremity; Pharyngitis; Prostatic Disorder; Pruritus; Rash; Rash Erythematous; Rheumatoid Arthritis; Thermal Burn; Throat Tightness; Tooth Fracture; Tooth Infection; Vision Blurred; Weight	Rituxan			S	Intravenous (not otherwise specified)	Recent Dose On 06/Jul/2015 Last Rituximab Infusion 15/Feb/2016 Previous Rituxan Infusion: 12/Jun/201		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Atorvastatin			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Dexilant			C				Not Reported
	Acebutolol			C		Mylan		Not Reported
	Clopidogrel			C				Not Reported
	Oxycodone			C		Every Evening		Not Reported
	Tylenol			C	Oral			Not Reported
	Solu-Medrol			C	Intravenous (not otherwise specified)			Not Reported
	Xalatan			C				Not Reported
	Azarga			C				Not Reported
	Statex (Canada)			C				Not Reported

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	14908110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP013244			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Mobicox			S	Oral	7.5 Mg, Qd		Not Reported
	Actemra			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	15306822	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP018993		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity; Full Blood Count Decreased; Gastrointestinal Disorder; Intentional Product Misuse; Malaise; Sjogren'S Syndrome; Weight Decreased; White Blood Cell Count Decreased	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	10 Mg, Q.Wk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported

	Enbrel	S	Unknown	50 Milligram, Q.O.Wk. (Once Every Two Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	15333576	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019453		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Apo-Leflunomide			S	Oral	10 Milligram		Apotex
	Apo-Leflunomide			S	Unknown	5 Milligram		Apotex
	Leflunomide			S	Unknown	5 Mg, Unk (Therapy Duration: 365 Unit Unknown)		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Apotex
	Cimzia			S	Subcutaneous	200 Milligram, Q.O.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Cyclical		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	50 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	15337014	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019548		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk, Therapy Duration: 59		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	160 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	190 Mg, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Other	80 Mg, Qd		Not Reported
	Methylprednisolone Acetate			C	Other	80 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	15727088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Sulfasalazine	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous drip	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	15795569	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1900590US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Risedronate Sodium - Bp			S	Oral	35 Mg, Q Week		Allergan
	Actonel			S		35 Mg, Q Week		Allergan
	Methotrexate			S	Subcutaneous	17.5 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Cyclical		Not Reported

Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide	S	Unknown	20 Mg, Q1hr	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Plaquenil	S	Oral	300 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclical	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	100 Mg	Not Reported
	Arava	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Gold	S			Not Reported
	Hydroxychloroquine	S		300 Mg, Qd	Not Reported
	Hydroxychloroquine	S		1 Df, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S		5 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	16211394	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020276		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Mobicox	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Depo Medrol	C	Intra-articular	80 Milligram	Not Reported
	Depo Medrol	C	Intramuscular	80 Milligram, Once A Day	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	16281597	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2771777-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	16666299	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2872314-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Stenosis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol + Acetaminofen			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Tramacet			S	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

	Nortriptyline Hydrochloride	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Lorazepam	C	Unknown		Not Reported
	Depomedrol	C	Intramuscular	Form Of Administration - Suspension Intraarticular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17422933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17543214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb

Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound			otherwise specified)		
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported

	Tocilizumab	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17683933	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100719			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Colectomy; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure; Treatment Failure	Plaquenil			S	Unknown	Unk		Sanofi
	Arava			S	Unknown			Sanofi
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported

	Humira	S	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17683938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100724			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Plaquenil			S	Unknown	Unk		Sanofi
	Bisoprolol Salt Not Specified			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Sanofi
	Zopiclone			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17684209	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA100717			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Sulfasalazine			S				Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Acetaminophen			S				Not Reported
	Actemra			S	Unknown			Not Reported

Somnolence; Visual Impairment	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Methotrexate	C	Unknown	1 Df, Qw	Not Reported
	Meloxicam	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17687721	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100758			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Finger Deformity; Hand Deformity; Infection; Malaise; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Tendon Rupture	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate Sodium			S				Not Reported
	Simponi			S				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17805801	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598742		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Condition Aggravated; Cough; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Viral Infection	Celebrex	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17835058	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	In Pre-Filled Syringe	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17851614	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Actonel			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	17917175	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020232040		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyshidrotic Eczema; Eczema; Off Label Use; Product Use In Unapproved Indication; Pruritus	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2 Df, 1x/Day		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	1 Df, 1x/Day		Not Reported
	Kaletra			S	Oral	2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18029504	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-22067		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported

Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen	S	Unknown	Unknown		Not Reported
	Orencia	S	Unknown			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18035476	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-03242		62 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Oseltamivir			S	Unknown	Unk		Lupin
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	40 Milligram, Qd		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Milligram, Bid		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk (Gradually Reduced And Discontinued)		Lupin
	Arbidol			S	Unknown	Unk		Not Reported
	Piperacillin / Tazobactam			S	Intravenous (not otherwise specified)	4.5 Gram, Tid		Not Reported

	Acetylcysteine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18069971	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202007007244			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18092011	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1806024		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteonecrosis	Prednisone			S	Unknown	At The Time Of His Visit Patient'S Regimen Included Prednisone 10 Mg		Actavis
	Prednisone			S	Unknown	Due To Signs Of Active Disease, The Patient Was Told To Increase Prednisone To 40 Mg And Start A ...		Actavis
	Prednisone			S	Unknown	3 Milligram Daily; Currently Tolerating A Slow Taper, Now On 3 Mg Per Day		Actavis
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown	200 Milligram Daily; Dose Of Azathioprine Was Titrated Up To 100mg Twice A Day		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18097888	EXPEDITED (15-DAY)		DE, HO, LT	CA-ACCORD-193341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Single Use Vial, Dosage Form: Powder For Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxyquinoline Sulfate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Single Use Vial		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18101335	EXPEDITED (15-DAY)		OT	CA-ACCORD-193683		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18117855	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1810002		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Mycophenolate Mofetil			S	Unknown			Teva
	Prednisone			S	Unknown	9 Milligram Daily;		Actavis
	Tacrolimus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18122625	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1810074		11 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Respiratory Depression; Victim Of Child Abuse	Aripiprazole			S	Oral	Administered Three Times Daily		Teva
	Celecoxib			S	Oral	200 Milligram Daily;		Teva
	Clonidine			S	Oral	Dose: 0.05mg Every Morning And 0.1 Mg Every Evening		Actavis
	Diphenhydramine			S	Oral	50 Milligram Daily; Administered Every 6 Hours As Required		Barr
	Fluoxetine			S	Oral	20 Milligram Daily;		Barr
	Fluticasone			S	Respiratory (inhalation)	2 Dosage Forms Daily; Dose: 250microg Per Actuation; 2 Puffs Daily		Teva
	Gabapentin			S	Oral	1800 Milligram Daily; Administered Three Times Daily		Ivax
	Montelukast			S	Oral	10 Milligram Daily;		Teva
	Pantoprazole			S	Oral	40 Milligram Daily;		Teva
	Ranitidine			S	Oral	150 Milligram Daily;		Actavis
	Salbutamol Sulfate			S	Respiratory (inhalation)	12 Dosage Forms Daily; Dose: 100microg Per Actuation; 2 Puffs Every 4 Hours As Required		Barr
	Ascorbic Acid-Ascorbate Sodium			S	Oral	1500 Milligram Daily; Ascorbic Acid-Ascorbate Sodium		Not Reported
	Baclofen			S	Oral	60 Milligram Daily; Administered Three Times Daily		Not Reported

Bisacodyl	S	Oral	5 Milligram Daily; Administered Daily As Required	Not Reported
Colecalciferol	S	Oral	2000 Iu (International Unit) Daily;	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
Ketorolac	S	Oral	80 Milligram Daily; Administered Every 6 Hours As Required	Not Reported
Leuprorelin	S	Intramuscular		Not Reported
Lorazepam	S	Sublingual	Dose: 0.5mg And 2mg, As Required	Not Reported
Melatonin	S	Oral	10 Milligram Daily; Administered Every Night	Not Reported
Methocarbamol-Acetaminophen	S	Oral		Not Reported
Methadone	S	Oral	6 Milligram Daily; Administered Three Times Daily	Not Reported
Hydromorphone	S	Unknown	Immediate Release	Not Reported
Omega 3-Dha-Epa-Fish Oil [Doconexent\Icosapent\Omega-3 Fatty Acids]	S	Oral	Omega 3-Dha-Epa-Fish Oil	Not Reported
Phenobarbital	S	Oral	60 Milligram Daily;	Not Reported
Polyethylene Glycol	S	Oral	60 Milligram Daily;	Not Reported
Clobazam	S	Oral	40 Milligram Daily;	Teva
Dimenhydrinate	S	Oral	50 Milligram Daily; Administered Every 6 Hours As Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18147166	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-04			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox	S	Oral			Boehringer Ingelheim
	Cosentyx	S	Oral			Not Reported
	Diclofenac	S	Oral			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Golimumab	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leucovorin Calcium	S	Oral			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Otezla	S	Unknown			Not Reported
	Pantoprazole	S	Oral			Not Reported
	Pantoprazole Magnesium	S	Unknown			Not Reported
	Synthroid	S	Unknown			Not Reported
	Diltiazem Hydrochloride	C	Oral			Not Reported
	Fluticasone Propionate	C	Respiratory (inhalation)			Not Reported
	Mar-Pantoprazole	C	Unknown	Dosage Form: Tablet (Delayed Release)		Not Reported
	Mometasone Furoate	C	Unknown			Not Reported
	Premarin	C	Unknown			Not Reported
	Salbutamol	C	Respiratory (inhalation)			Not Reported
	Tramadol Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18147555	NON-EXPEDITED			US-ADVANZ PHARMA-202008007720			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Dyspnoea; Pain In	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		2 Dosage Form, Bid		Concordia

Extremity; Palpitations; Product Quality Issue; Skin Burning Sensation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Unk	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18148520	EXPEDITED (15-DAY)		HO, LT	RO-AUROBINDO-AUR-APL-2020-038674		58 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	800 Milligram,2 Administrations		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18148755	EXPEDITED (15-DAY)		OT	CA-ROCHE-2657772		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Rabeprazole			C	Unknown			Not Reported

	Simponi	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18148816	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04495		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Azathioprine			C	Unknown	Unk		Not Reported
	Immunoglobulin [Immunoglobulins Nos]			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18148923	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-037		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Drug Ineffective; Hangover; Headache; Major Depression; Malaise; Vomiting; Weight Increased	Methotrexate			S	Unknown	Unknown		Westward
	Methotrexate			S	Unknown	Unknown		Westward
	Prednisone			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Meloxicam			S	Unknown	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Tylenol			C	Unknown	Unknown		Not Reported
	White Blood Cells			C	Intravenous (not	Unknown		Not Reported

	Ibuprofen			C	otherwise specified) Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18148936	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25249			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149462	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010310			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149472	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010311			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Orthostatic Hypotension; Palmoplantar Pustulosis; Presyncope; Rash; Red Blood Cell Sedimentation Rate Increased; Retinopathy	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149473	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Humira	C	Unknown		Not Reported
	Pantoloc	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149589	EXPEDITED (15-DAY)		OT	IT-BEH-2020120939			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Human Immunoglobulin (Inn)			S	Transplacental			Csl Behring
	Hydroxychloroquine			S	Transplacental			Not Reported
	Aspirin (E.C.)			S	Transplacental			Not Reported
	Low Molecular Weight Heparin Sodium			S	Transplacental			Not Reported
	Insulin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149819	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-065072		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	1000 Milligram, Qd		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported
	Losec [Omeprazole]			C	Unknown			Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149909	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-038793		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Delftia Acidovorans Infection; Device Related Sepsis; Enterococcal Infection; Incorrect Route Of Product Administration; Pneumonia Bacterial; Pseudomonas Infection; Septic Shock; Staphylococcal Infection	Azithromycin Film-Coated Tablets			S	Oral	250 Milligram		Aurobindo
	Azithromycin Film-Coated Tablets			S	Intravenous (not otherwise specified)	250 Milligram		Aurobindo
	Sarilumab			S	Subcutaneous	400 Milligram, Once A Day		Not Reported
	Plaquenil			S	Intravenous (not otherwise specified)	600 Milligram, Once A Day		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Cloxacillin			C	Unknown	Unk		Not Reported
	Meropenem			C	Unknown	Unk		Not Reported
	Meropenem			C				Not Reported
	Meropenem			C				Not Reported
	Cyamemazine			C	Unknown	Unk		Not Reported
	Caspofungin			C	Unknown	Unk		Not Reported
	Caspofungin			C	Unknown	Unk		Not Reported
	Caspofungin			C				Not Reported
	Caspofungin			C				Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported
	Amlor			C	Unknown	Unk		Not Reported
	Sevoflurane			C	Unknown	Unk		Not Reported
	Vancomycin			C	Unknown	Unk		Not Reported
	Vancomycin			C				Not Reported
	Vancomycin			C				Not Reported
	Amikacin			C	Unknown	Unk		Not Reported
	Amikacin			C	Unknown	Unk		Not Reported
	Amikacin			C				Not Reported
	Amikacin			C				Not Reported

	Ramipril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149917	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-038979		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jugular Vein Thrombosis; Pneumonia Bacterial; Staphylococcal Bacteraemia; Staphylococcal Infection; Thrombosis	Azithromycin Film-Coated Tablets			S	Oral	250 Milligram, Once A Day		Aurobindo
	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported
	Amiklin			C	Unknown	Unk		Not Reported
	Diprivan			C	Unknown	Unk		Not Reported
	Tazocilline			C	Unknown	Unk		Not Reported
	Heparine			C	Unknown	Unk		Not Reported
	Hypnovel			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Lasilix			C	Unknown	Unk		Not Reported
	Noradrenaline			C	Unknown	Unk		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Sufenta			C	Unknown	Unk		Not Reported
	Tracrium			C	Unknown	Unk		Not Reported
	Umuline			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149941	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020313920		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported
	Hydroxychloroquine			S		800 Mg (Loading Dose)		Not Reported
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Daily		Not Reported
	Heparin			C		Unk (Continuous Infusion)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149946	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-022353		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acid Fast Bacilli Infection; Bacterial Infection; Bone Abscess; Cachexia; Calcinosis; Chills; Decreased Appetite; Delirium; Dermal Sinus; Disseminated Mycobacterium Avium Complex Infection; Enterobacter Infection; Pain; Pain In Extremity; Peptostreptococcus Infection; Pyrexia; Sepsis; Skin Bacterial Infection; Skin Lesion; Weight Decreased	Prednisolone			S	Unknown			Bausch And Lomb
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Immunoglobulin			C				Not Reported
	Rivaroxaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149949	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020313775		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Daily	Pfizer
	Ceftriaxone	S	Intravenous (not otherwise specified)	1 G, Daily	Not Reported
	Hydroxychloroquine	S		800 Mg (Loading Dose)	Not Reported
	Hydroxychloroquine	S		400 Mg, Daily	Not Reported
	Heparin	C		Unk (Continuous Infusion Of Unfractionated Heparin)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150030	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020308601		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	60 Mg, Daily		Pfizer
	Methylprednisolone Sodium Succinate			S				Pfizer
	Methylprednisolone Sodium Succinate			S				Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported
	Ceftriaxone			S				Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S		800 Mg (Loading Dose)		Not Reported
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Hydroxychloroquine			S				Not Reported
	Oxygen			C	Nasal	2 L (Placed On 2 L Of Supplemental Oxygen Via Nasal Cannula)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150102	EXPEDITED (15-DAY)		OT	IT-SGP-000006		60 YR	Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Covid-19 Pneumonia; Lymphopenia; Product Use In Unapproved Indication; Thrombocytopenia	Methylprednisolone			S	Unknown			Sungen Pharma
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150278	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202008007807			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Joint Dislocation; Product Administration Interrupted; Purpura; Rash Macular; Suspected Covid-19	Hydroxychloroquine			S		200 Mg, Three Times A Day		Concordia
	Xeljanz Xr			S		11 Mg, One Per Day		Not Reported
	Naproxen			S		500 Mg, As Needed		Not Reported
	Xanax			S		0.5 Mg, Twice A Day		Not Reported
	Centrum			S		Once A Day		Not Reported
	Clonazepam			S		1 Mg, Once A Day		Not Reported
	Doxycycline Monohydrate			S		100 Mg, Once A Day		Not Reported
	Lexapro			S		20 Mg, Once A Day		Not Reported
	Levetiracetam			S		Unk		Not Reported
	Pregabalin			S		150 Mg, Two Times A Day		Not Reported
	Rivastigmine			S		One Patch Every 24 Hours		Not Reported
	Spironolactone			S		Unk		Not Reported
	Methocarbamol			S		500 Mg, Twice A Day		Not Reported
	Tizanidine			S		4 Mg, Twice A Day		Not Reported

	Alphagan P	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150312	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-04639		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150419	EXPEDITED (15-DAY)		OT	AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2020-04602			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Graft Versus Host Disease	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	Unk		Alkem
	Tacrolimus			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sirolimus			S	Unknown	Unk		Not Reported
	Cyclosporin-A			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150696	EXPEDITED (15-DAY)		DE, HO, OT	US-MYLANLABS-2020M1071539		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Multiple Organ Dysfunction Syndrome; Off Label Use; Pneumonia	Prednisone	S	Unknown	15 Milligram, Qd	Mylan
	Prednisone	S	Unknown	40 Milligram, Qd	Mylan
	Prednisone	S	Unknown	20 Milligram, Qd	Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Mylan
	Hydroxychloroquine	S			Mylan
	Cyclosporine	S	Unknown	175 Milligram, Bid	Mylan
	Cyclosporine	S			Mylan
	Pyridostigmine	C	Unknown	60 Milligram, Qid	Mylan
	Immunoglobulin /00025201/	C	Intravenous (not otherwise specified)	2g/Kg	Mylan
	Immunoglobulin /00025201/	C			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150743	EXPEDITED (15-DAY)		OT	CA-ACCORD-195042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150751	EXPEDITED (15-DAY)		OT	CA-ACCORD-195256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150761	EXPEDITED (15-DAY)		OT	CA-ACCORD-195258			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Humira			C	Unknown	Dosage Form: Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150947	EXPEDITED (15-DAY)		DS	CA-ACCORD-195317		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150948	EXPEDITED (15-DAY)		HO	CA-ACCORD-195325		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous 2 Every 1 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form:Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days	Not Reported
	Desoximetasone	C		Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150954	EXPEDITED (15-DAY)		OT	CA-ACCORD-195262			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown	Not Specified 1 Every 1 Weeks		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150958	EXPEDITED (15-DAY)		OT	CA-ACCORD-195326		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate	S	Unknown	Not Specified	Accord
	Actemra	S	Intravenous (not otherwise specified)	Not Specified	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Specified	Not Reported
	Calcium Carbonate	C			Not Reported
	Cetirizine	C			Not Reported
	Cranberry	C			Not Reported
	Olopatadine/Olopatadine Hydrochloride	C		Not Specified	Not Reported
	Prednisone	C		Not Specified	Not Reported
	Quinapril	C			Not Reported
	Rabeprazole/Rabeprazole Sodium	C			Not Reported
	Singulair	C		Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151260	EXPEDITED (15-DAY)		OT	CA-ACCORD-195339		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rosuvastatin			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S				Not Reported

Failure	Rosuvastatin	S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18152091	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-25235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Cimzia Single-Use Pre Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18152365	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1071693		33 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Covid-19; Diarrhoea; Febrile Neutropenia; Off Label Use; Pancytopenia	Paclitaxel			S	Unknown	Along With Ifosfamide		Mylan
	Paclitaxel			S				Mylan
	Paclitaxel			S				Mylan
	Ritonavir			S	Oral	100 Milligram, Qd		Unknown
	Darunavir			S	Oral	800 Milligram, Qd		Not Reported
	Ifosfamide			S	Unknown	Along With Paclitaxel		Mylan

Ifosfamide	S				Mylan
Ifosfamide	S				Mylan
Carboplatin	S	Unknown	Area Under The Concentration-Time Curve (Auc) 7 Along With...		Mylan
Carboplatin	S				Mylan
Carboplatin	S				Mylan
Etoposide	S	Unknown	400 Mg/Sqm Along With...		Mylan
Etoposide	S				Mylan
Etoposide	S				Mylan
Hydroxychloroquine	S	Oral	200 Milligram, Bid		Mylan
Levofloxacin	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18152554	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Rituximab		S	otherwise specified) Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18152558	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-065748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18152952	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-065837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure;	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Vomiting	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2020	18040522	EXPEDITED (15-DAY)		OT	BR-GILEAD-2020-0483586		46 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Anosmia; Antiphospholipid Syndrome; Anxiety; Covid-19; Decreased Appetite; Dyspnoea; Fatigue; Feeding Disorder; Headache; Immune Thrombocytopenia; Insomnia; Ischaemic Stroke; Malaise; Nausea; Pain; Patient Isolation; Platelet Count Decreased; Pulmonary Hypertension; Weight Decreased	Ambrisentan			S	Unknown	10 Mg, 1d		Gilead
	Ambrisentan			S				Gilead
	Furosemide			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Puran T4			S	Unknown	Unk		Not Reported
	Marevan			S	Unknown	Unk		Not Reported
	Reuquinol			S	Unknown	Unk		Not Reported
	Reuquinol			S				Not Reported
	Sildenafil			S	Unknown	Unk		Not Reported
	Cardizem			C		Unk		Not Reported
	Cardizem			C		Unk		Not Reported
	Bosentan			C		Unk		Not Reported
	Bosentan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2020	18153157	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2020158031		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Mobility Decreased; Musculoskeletal Pain;	Benlysta			S	Intravenous (not otherwise specified)	800 Mg		Glaxosmithkline

Myalgia; Pain In Extremity	Cellcept		S	Unk	Not Reported
	Plaquenil		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2020	18155476	DIRECT		OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Chills; Dizziness; Dyspnoea; Fatigue; Headache; Heart Rate Irregular; Myalgia; Palpitations; Pyrexia; Suspected Covid-19; Vomiting	Hydroxychloroquine Sulfate Tablets			S	Oral	Quantity:1 Tablet(S);	1 MIN	Shanghai Pharma Group Changzhou Kony Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	15589215	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3173		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Minocycline	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Otezla	S	Unknown	Not Reported
Otezla	S	Oral	Not Reported
Otezla	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Sirukumab	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Morphine Sulfate	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Etanercept	S	Unknown	Not Reported
Infliximab Hopsira	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Golimumab	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

	Ustekinumab	S	Subcutaneous	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Bupropion Hydrochloride	C	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	17981278	EXPEDITED (15-DAY)		OT	NVSC2020FR185500		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	Unk		Novartis
	Amiodarone Hydrochloride			S	Unknown	Unk		Not Reported
	Spiramycin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Sarilumab			S	Subcutaneous	400 Mg (400 Mg, 1x)		Not Reported
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Hydroxyzine			C	Unknown	Unk		Not Reported
	Monoprost			C	Unknown	Unk		Not Reported
	Gabapentine			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Eplerenone			C	Unknown	Unk		Not Reported
	Tamsulosine			C	Unknown	Unk		Not Reported

Clopidogrel	C	Unknown	Unk		Not Reported
Oxazepam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	18153550	NON-EXPEDITED			US-SA-2020SA212458			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Musculoskeletal Stiffness; Pain; Therapy Cessation	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	18153700	EXPEDITED (15-DAY)		LT	NVSC2020FR223321		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cellulitis Staphylococcal; Delftia Acidovorans Infection; Device Related Sepsis; Enterococcal Infection; Incorrect Route Of Product Administration; Pneumonia Bacterial; Pseudomonas Infection; Septic Shock; Septic Shock	Azithromycin			S	Oral	250 Mg (Zithromax 250 Mg Coated Tablet)		Novartis
	Sarilumab			S	Subcutaneous	400 Mg, Qd		Not Reported
	Plaquenil			S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Cloxacilline			C	Unknown	Unk		Not Reported
	Tercian			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported
	Amlor			C	Unknown	Unk		Not Reported
	Sevoflurane			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	12890992	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013491		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk, Unknown		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk, Unknown		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Voltaren /00372301/			C	Unknown	100 Mg, Qd		Not Reported
	Cortisone			C	Unknown	10 Mg, Qd		Not Reported
	Desoximetasone			C	Oral	10 Mg, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Subcutaneous			Not Reported
	Diclofenac			C	Unknown	100 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	13057660	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015709		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pneumonia; Product Dose Omission; Rheumatoid Arthritis; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine	S	Oral	400 Mg, Unk	Apotex
	Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Apotex
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	1 Dosage Form	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
	Estradiol	C	Unknown	0.6 %, Tid	Not Reported
	Furosemide	C	Unknown	40 Mg, Qd	Not Reported
	Valsartan	C	Unknown	320 Mg, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Mg, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd	Not Reported
	Baclofen	C	Unknown	10 Milligram, Bid	Not Reported
	Levaquin	C	Unknown	500 Milligram, Qd	Not Reported
	Calcium	C	Unknown	500 Mg, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qd	Not Reported
	Ergocalciferol	C	Unknown	1 Dosage Form, Q.Wk.	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
	Zingiber Officinale	C	Unknown	500 Mg, Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

	Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
	Methotrexate	C	Unknown	15 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	13103523	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876554		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intra-arterial			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Apo Mycophenolate			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C		Not Reported
	Piroxicam	C		Not Reported
	Leflunomide	C		Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	13657154	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2017SA105779			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue;	Hydroxychloroquine			S	Oral	200 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	200 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg,Qw		Not Reported
	Alendronate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg		Not Reported
	Methotrexate			S	Oral	10 Mg,Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Methotrexate			S		12 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Q4w		Not Reported
	Methotrexate			S		12.5 Mg, Q4w		Not Reported

Pruritus; Rash; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate	S		12 Mg	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Methotrexate	S		17.5 Mg, Qw	Not Reported
	Methotrexate	S		15 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Q4w	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q4w	Not Reported
	Methotrexate	S	Oral	25 Mg, Qw	Not Reported
	Alendronic Acid	S		70 Mg, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qm	Not Reported
	Myochrysine	S	Parenteral	50 Mg, Qm	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qw	Not Reported

Arava	S			Sanofi
Methotrexate Sodium	S	Oral	10 Mg, Qow	Not Reported
Actemra	S	Unknown	680 Mg,Qm	Not Reported
Actemra	S	Unknown	360 Mg,Qm	Not Reported
Actemra	S		380 Mg	Not Reported
Actemra	S		360 Mg, Qm	Not Reported
Enbrel	S	Unknown	50 Mg,Biw	Not Reported
Enbrel	S	Unknown	25 Mg,Biw	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S		50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
Humira	S		40 Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Unknown	780 Mg,Qw	Not Reported
Orencia	S		780 Mg	Not Reported
Orencia	S		780 Mg, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Remicade	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported

	Tocilizumab		S		680 Mg, Q4w	Not Reported
	Ciclosporin		C	Unknown	150 Mg,Qd	Not Reported
	Prednisolone		C	Unknown	10 Mg,Unk	Not Reported
	Prednisone		C	Unknown	10 Mg,Qd	Not Reported
	Prednisone		C		10 Mg, Qd	Not Reported
	Xeljanz		C			Not Reported
	Alendronate Sodium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	14509798	NON-EXPEDITED			US-PFIZER INC-2018045863			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		1000 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported
	Leflunomide			S		10 Mg, 1x/Day		Not Reported
	Humira			S		40 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Xeljanz Xr			C	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	16064779	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05686		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported

			Subcutaneous	
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown, Tablet Usp	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Unknown	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Desoximetasone	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	16128012	EXPEDITED (15-DAY)		OT	PHHY2019CA064350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported

Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	Unk, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	17839754	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Rituximab	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Benzalkonium Chloride	S	Unknown	Not Reported
	Boric Acid	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Disodium Edetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phenylephrine Hydrochloride	S	Intramuscular	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Borate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	Not Reported
	Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Disodium Edetate	S	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	17853763	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606293		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Gastric Disorder; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S				Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Cyclosporin A			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ibuprofen	S	Oral	Not Reported
	Infliximab	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Intramuscular	Not Reported

Myochrysine	S	Intramuscular	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Otezla	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Sulfasalazine	S	Endocervical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	17928629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2623109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	17934410	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012491			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neuropathy Peripheral	Ibuprofen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18043486	EXPEDITED (15-DAY)		DS	CA-ROCHE-2641921		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic	Actemra			S	Unknown			Not Reported

Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Indocid	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Cymbalta	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18090863	EXPEDITED (15-DAY)		OT	CA-ACCORD-192703		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Ergocalciferol			C				Not Reported
	Folinic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Folinic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18099266	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202007007494			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disturbance In Attention; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Stress; Visual Impairment	Hydroxychloroquine			S	Unknown			Concordia
	Kevzara			S	Subcutaneous	200 Mg, Qow, Every Two Weeks		Not Reported
	Kevzara			S	Subcutaneous	150 Mg, Qow		Not Reported
	Kevzara			S	Subcutaneous	150 Mg, Q10d		Not Reported
	Kevzara			S	Subcutaneous	200 Mg, Qow		Not Reported

Prednisone	C		Not Reported
Tecta	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18101341	EXPEDITED (15-DAY)		OT	CA-ACCORD-193685			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Pain; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			S	Oral	1 Every 24 Hours		Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Tiaprofenic Acid			C	Unknown	Not Specified		Not Reported
	Acetylsalicylic Acid			C	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Methotrexate			S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18114341	NON-EXPEDITED			US-AMGEN-USASP2020126000		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindication To Medical Treatment; Drug Ineffective; Drug Intolerance	Enbrel	S	Unknown	50 Mg	Amgen
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rinvoq	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18122075	EXPEDITED (15-DAY)		HO	CA-ACCORD-194572		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord
	Gabapentin			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Months		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S		Frequency: 1 Every 1 Weeks		Not Reported
	Fentanyl			S				Not Reported
	Hydroxychloroquine			S		Frequency: 1 Every 24 Hours		Not Reported
	Myochrysine			S	Intramuscular	Frequency:1 Every 3 Weeks		Not Reported
	Nortriptyline			S	Oral			Not Reported
	Orencia			S	Vaginal	Frequency: 1 Every 1 Months		Not Reported
	Oxycontin			S				Not Reported
	Sulfasalazine			S	Oral	Frequency: 1 Every 24 Hours		Not Reported

Tylenol	C				Not Reported
Trazodone	C				Not Reported
Risedronic Acid	C				Not Reported
Prednisone	C				Not Reported
Perphenazine	C				Not Reported
Pantoprazole	C				Not Reported
Oxycodone	C				Not Reported
Nasonex	C		Dosage Form: Spray, Metered Dose		Not Reported
Loperamide	C				Not Reported
Lomotil	C				Not Reported
Iron	C				Not Reported
Esomeprazole	C				Not Reported
Ergocalciferol	C				Not Reported
Aclasta	C	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
Nortriptyline	C				Not Reported
Omega 3	C				Not Reported
Gabapentin	S	Oral	2 Every 1 Days		Not Reported
Myochrysine	S	Intramuscular	Frequency:1 Every 3 Weeks		Not Reported
Trazodone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18122249	EXPEDITED (15-DAY)		OT	CA-ACCORD-194337			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18145053	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2020312009			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154257	EXPEDITED (15-DAY)		OT	CA-ROCHE-2656556		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154261	EXPEDITED (15-DAY)		HO	CA-ROCHE-2656581			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154342	EXPEDITED (15-DAY)		HO	FR-ABBVIE-20K-056-3524397-00		29 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Oral	Dosage Detailed In The Commentary		Not Reported

	Augmentin	C			Not Reported
	Lovenox	C		Solution Injectable In Ampoule	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154439	EXPEDITED (15-DAY)		HO, LT	RO-AUROBINDO-AUR-APL-2020-038673		35 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Condition Aggravated; Drug Ineffective; Gastric Disorder; Gastrointestinal Disorder; Haemoptysis; Off Label Use; Vomiting	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Meropenem			S	Unknown	Unk		Aurobindo
	Dexamethasone			S	Unknown	16 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	800 Milligram,3 Administrations		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154460	EXPEDITED (15-DAY)		OT	JP-LUPIN PHARMACEUTICALS INC.-2020-04551		67 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	250 Milligram, Bid (For Three Days)		Lupin
	Hydrocortisone			S	Unknown	200 Milligram Loading Dose, Followed By 240 Mg Daily For 7 Days		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154513	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04496		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154555	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04497		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Single		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Lupin
	Cefepime			C	Unknown	Unk (Stopped)		Not Reported
	Levofloxacin			C	Unknown	Unk (Stopped)		Not Reported
	Zinc Sulfate			C	Oral	220 Milligram, Tid		Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral	1 Gram, Bid		Not Reported
	Vitamin C [Ascorbic Acid]			C	Intravenous (not otherwise specified)	11 Gram, Qd (Infusion)		Not Reported
	Norepinephrine			C	Unknown	0.02 Mcg/Kg/Min (Stopped)		Not Reported
	Colchicine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154630	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-04846		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

	Lopinavir + Ritonavir	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	20 Milligram, Qd	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154705	EXPEDITED (15-DAY)		OT	CA-ACCORD-195478			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S				Accord
	Actemra			S		1 Every 1 Weeks		Not Reported
	Arava			S				Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Cimzia			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154708	EXPEDITED (15-DAY)		HO	CA-ACCORD-195479			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Gabapentin			S	Oral	2 Every 1 Days		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Celebrex			S	Occlusive dressing			Not Reported

Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Renal Impairment; Skin Lesion; Treatment Failure			technique		
	Enbrel	S		1 Every 1 Weeks	Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid	S			Not Reported
	Fentanyl	S			Not Reported
	Myochrysine	S	Intramuscular	1 Every 3 Weeks	Not Reported
	Hydroxychloroquine	S		1 Every 1 Days	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Every 3 Weeks	Not Reported
	Oxycontin	S			Not Reported
	Xeljanz	S			Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days	Not Reported
	Thiamine	S		100 Mg	Not Reported
	Iron	C			Not Reported
	Iron	C			Not Reported
	Biotin	C			Not Reported
	Aclasta	C			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	C			Not Reported
	Colecalciferol	C			Not Reported
	Ascorbic Acid	C			Not Reported
	Ergocalciferol	C			Not Reported
	Folic Acid	C			Not Reported
	Lomotil	C			Not Reported
	Nasonex	C			Not Reported
	Nicotinamide	C			Not Reported
	Nortriptyline	C			Not Reported
	Pantoprazole	C			Not Reported
	Retinol	C			Not Reported
	Riboflavin	C			Not Reported
	Risedronic Acid	C			Not Reported
	Thiamine	C			Not Reported
	Trazodone	C			Not Reported
	Tylenol	C			Not Reported
	Pyridoxine	C			Not Reported
	Ascorbic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154756	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04610		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk		Lupin
	Norepinephrine			C	Unknown	Unk		Not Reported
	Vasopressin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154907	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-04607			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pneumonia	Oseltamivir			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ribavirin			S	Unknown	Unk		Not Reported
	Arbidol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18154941	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04620		22 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pruritus	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Loading Dose)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram Weekly		Lupin
	Cetirizine			S	Oral	10 Milligram, Qd		Novel Labs
	Doxepin			C	Oral	20 Milligram, Qd (At Bed Time)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18155049	EXPEDITED (15-DAY)		OT	IN-LUPIN LIMITED-2020-04622		26 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pruritus; Rash Maculo-Papular; Urticaria	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Loading Dose)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram Weekly		Lupin
	Cetirizine			S	Oral	10 Milligram, Qd		Novel Labs
	Cetirizine			S				Novel Labs
	Cetirizine			S				Novel Labs
	Doxepin			C	Oral	20 Milligram, Qd		Not Reported
	Doxepin			C				Not Reported
	Doxepin			C				Not Reported
	Methylprednisolone			C	Unknown	16 Milligram		Not Reported
	Methylprednisolone			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18155757	EXPEDITED (15-DAY)		OT	BE-ADVANZ PHARMA-202008007700			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nervous System Disorder	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18155793	EXPEDITED (15-DAY)		OT	CA-ACCORD-195501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis;	Methotrexate			S	Unknown	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous	Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Desoximetasone		C	Unknown	Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18155794	EXPEDITED (15-DAY)		OT	CA-ACCORD-195500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	Not Specified		Not Reported
	Remicade			S	Unknown	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156106	EXPEDITED (15-DAY)		OT	CA-ACCORD-195490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156107	EXPEDITED (15-DAY)		OT	CA-ACCORD-195488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Prednisone			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
Fosamax	S	Oral			Not Reported
Folic Acid	S	Unknown			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Cimzia	S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
Arava	S	Oral			Not Reported
Actemra	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156108	EXPEDITED (15-DAY)		OT	CA-ACCORD-195491		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	1 Every 6 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Every 6 Months		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Risedronic Acid			C	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156109	EXPEDITED (15-DAY)		OT	CA-ACCORD-195489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cortisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156114	EXPEDITED (15-DAY)		HO, LT	CA-ACCORD-195484			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Subcutaneous,Single-Use Vial		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156116	EXPEDITED (15-DAY)		OT	CA-ACCORD-195480			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous,Single-Use		Not Reported

Enbrel	S	Subcutaneous			Not Reported
Folic Acid	S	Unknown			Not Reported
Fosamax	S	Unknown			Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Reactine [Cetirizine]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Intravenous		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156307	EXPEDITED (15-DAY)		OT	CA-ACCORD-195504		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	C	Unknown	Not Specified		Not Reported
Wellbutrin	C	Oral			Not Reported
Xeljanz	C	Unknown			Not Reported
Methotrexate	S	Unknown	Not Specified		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156646	EXPEDITED (15-DAY)		OT	NVSC2020CA224094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cosentyx			S	Unknown	Unk Unk, Unknown		Novartis
	Etanercept			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Diclofenac Sodium			S	Unknown	Unk Unk, Unknown		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unknown		Not Reported
	Calcium			S	Unknown	Unk Unk, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

Plaquenil	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Calcium Gluconate	C	Unknown	Unk Unk, Unknown		Not Reported
Quetiapine	C	Unknown	Unk Unk, Unknown		Not Reported
Pantoprazole	C	Unknown	Unk Unk, Unknown		Not Reported
Ramipril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156713	EXPEDITED (15-DAY)		OT	CH-LUPIN PHARMACEUTICALS INC.-2020-04676		10 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156717	EXPEDITED (15-DAY)		OT	CH-LUPIN PHARMACEUTICALS INC.-2020-04760		10 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156770	EXPEDITED (15-DAY)		DS	CA-ACCORD-195476		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling	Methotrexate			S	Oral			Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Days		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156771	EXPEDITED (15-DAY)		OT	CA-ACCORD-195477		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156924	EXPEDITED (15-DAY)		OT	CA-ACCORD-195264		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate			S	Oral			Accord
	Apo-Hydroxyquine			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Neoral			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Ciclosporin			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			S	Oral			Accord
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Neoral			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156927	EXPEDITED (15-DAY)		HO	CA-ACCORD-195260		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Alendronate Sodium/Alendronic Acid			S	Unknown			Accord
	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular	Dosage Form: Solution Intramuscular		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form:Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Ciclosporin			C		Not Specified		Not Reported
	Prednisone			C		Not Specified		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Methotrexate			S	Oral			Accord
	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Methotrexate			S	Subcutaneous			Accord
	Methotrexate			S	Subcutaneous			Accord

	Methotrexate		S	Subcutaneous	Accord
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156943	EXPEDITED (15-DAY)		OT	CA-ACCORD-195346		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	Not Specified		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Abatacept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18157732	EXPEDITED (15-DAY)		DE, OT	DE-JNJFOC-20200805585		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Simponi			S	Subcutaneous			Not Reported
	Maraviroc			S	Unknown			Not Reported

	Caspofungin	S	Unknown		Not Reported
	Piperacillin	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Tazobactam	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18157740	EXPEDITED (15-DAY)		DS	CA-ACCORD-195503			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18158998	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020317000			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Methotrexate Sodium			S	Unknown	20 Mg		Pfizer

Infection; Leukopenia; Lymphopenia; Rash; Serum Ferritin Increased; Systemic Lupus Erythematosus; Transient Ischaemic Attack; Treatment Failure	Actemra		S	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	600 Mg	Not Reported
	Atorvastatin Calcium		C	Unknown		Not Reported
	Bisoprolol		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Furosemide		C	Unknown		Not Reported
	Mycophenolate Sodium		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Ramipril		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18159990	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25373			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported

Increased; Septic Shock; Synovitis; Underdose; Vomiting	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18159998	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18160007	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25402			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18160015	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25437		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Product Use In Unapproved Indication; Product Use Issue; Septic Shock; Vomiting	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Anakinra		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Methotrexate		S	Unknown	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18160028	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-25483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intratumor			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single Use In Pre-Filled Syringe		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18161554	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3520258-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Disorder; Drug Ineffective; Drug-Induced Liver Injury; Fatigue; Gait Disturbance; Inflammation; Insomnia; Multiple Fractures; Musculoskeletal Stiffness; Nausea; Nephropathy Toxic	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18161731	EXPEDITED (15-DAY)		OT	CA-ROCHE-2657933		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	10551750	NON-EXPEDITED			US-PFIZER INC-2014296514		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer

Gabapentin	S	Unk	Pfizer
Hydroxyzine Pamoate	S	Unk	Pfizer
Pentazocine Lactate	S	Unk	Pfizer
Pregabalin	S	Unk	Pfizer
Adalimumab	S	Unk	Not Reported
Humira	S	Unk	Abbott
Abilify	S	Unk	Not Reported
Aripiprazole	S	Unk	Not Reported
Duloxetine	S	Unk	Not Reported
Fluoxetine	S	Unk	Not Reported
Pentazocine	S	Unk	Not Reported
Sumatriptan	S	Unk	Not Reported
Talwin Compound [Acetylsalicylic Acid;Pentazocine Hydrochloride]	S	Unk	Not Reported
Hydroxychloroquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	12881921	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013278		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	40 Milligram		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Naproxen Sodium Tablets			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Apotex
	Naproxen Sodium			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Aleve			S	Unknown	Unk		Not Reported

Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Unknown	12.5 Mg, Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Prednisone Acetate	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulphate	C	Unknown	Unk		Not Reported
Folic Acid	C	Subcutaneous	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	20 Mg, Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	12891630	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013462		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Swelling;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Swelling	Humira	S	Subcutaneous	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	C	Oral	50 Milligram	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	50 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	13057412	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015703		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	13057780	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP015710		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Aspirin /00002701/	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	5 Mg, Unk	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	13058991	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015722		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Off Label Use; Psoriasis; Pustular Psoriasis;	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Rheumatoid Arthritis; Scar; Vomiting	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Mg, Bid	Not Reported
	Aspirin /00002701/	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Penicillin G /00000901/	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	15711682	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587778-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	15899841	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019048311		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Immunodeficiency; Immunosuppression; Intentional Product Misuse; Nasal Congestion; Pain; Suspected Covid-19	Flector			S	Transdermal	1 Patch To Skin, Twice A Day		Pfizer
	Flector			S				Pfizer
	Diclofenac Sodium			S	Oral	Unk		Not Reported
	Oxymorphone			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Pennsaid			S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]			S		Unk		Not Reported
	Cbd			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	15926362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653493-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	16381260	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2805084-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Hypertensive Urgency; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness; Presyncope; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Oral			Not Reported

	Prednisone	S	Oral		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17287199	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-00706		365 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
Density Decreased; Bone Density Increased; C-Reactive Protein	Infliximab			S	Unknown			Not Reported
Abnormal; C-Reactive Protein Increased; Condition Aggravated;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Diarrhoea; Dizziness; Drug	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
Ineffective; Drug Intolerance; Drug Specific	Infliximab			S	Unknown	Unknown		Not Reported
Antibody; Gastroenteritis Viral; Human Antichimeric	Adalimumab			S	Subcutaneous	Unknown		Not Reported
Antibody Positive; Hypocalcaemia;	Adalimumab			S	Subcutaneous	Unknown		Not Reported
Hypokalaemia; Hypotension;	Adalimumab			S	Subcutaneous	Unknown		Not Reported
Immunodeficiency; Joint Destruction; Joint Effusion;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Joint Injury; Juvenile Idiopathic Arthritis; Liver	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Function Test Abnormal; Loss Of Consciousness; Loss Of Personal	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown. Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Immune Globulin Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Immune Globulin (Immune Globulin Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Immune Globulin Human)	S	Unknown	Unknown	Not Reported
	Immune Globulin (Immune Globulin Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Immune Globulin Human)	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Naproxen Sodium	S			Not Reported
	Orencia	S	Intravenous (not		Not Reported

		otherwise specified)		
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral	Unknown	Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Gamastan	S	Intramuscular	Liquid Intramuscular	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Immunoglobulin (Ivig)	S	Intravenous (not otherwise specified)		Not Reported
Immunoglobulins (Ivig)	S	Intravenous (not otherwise specified)		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-arterial	Unknown Suspension Intra Articular	Not Reported
	Triamcinolone Acetonide	S	Intra-arterial	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown Suspension Intra Articular	Not Reported
	Triamcinolone Acetonide	S	Oral	Suspension Intra Articular	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown. Duration: -31.0	Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17394735	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202002000642			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd (Film Coated Tablet) (Increased The Dose)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17722246	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia	S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported

	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17728614	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034852		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rash; Rheumatic Fever;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Prednison			S	Unknown	Unk		Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	25 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	0.5 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported

Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	400 Milligram, Qwk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Salazopyrine	S	Oral	1 Gram 2 Every 1 Day	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram 2 Every 1 Week	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported

Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Etanercept	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Otezla	S	Oral	3 Milligram 2 Every 1 Day	Not Reported
Otezla	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Topicort Lp	S	Oral		Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Winpred	S	Oral		Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Stelara	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Tofacitinib Citrate	C	Oral	5.0 Milligram, Qwk	Not Reported
Diclofenac	C	Unknown	50 Milligram, Qd	Not Reported
Salazopyrine	C	Oral	1 Gram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17873019	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2610855		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cardiac Disorder; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Unknown	Single Use, Powder For Injection	Not Reported
	Ilaris	S	Subcutaneous	Single Use Powder For Solution	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported

Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Oxycodone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Oral	Not Reported
Plaquenil	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17878882	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001752			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hydroxychloroquine Sulfate			S	Oral	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17903545	EXPEDITED (15-DAY)		OT	NVSC2020CA165483		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Unknown	3 Mg		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	17928952	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1057121		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyshidrotic Eczema; Eczema; Off Label Use; Pruritus	Azithromycin			S	Oral	500 Milligram, Qd		Mylan
	Enoxaparin Sodium			S	Subcutaneous	1 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18054569	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020276007		46 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Anosmia; Antiphospholipid Syndrome; Anxiety; Covid-19; Decreased Appetite; Dyspnoea; Fatigue; Feeding Disorder; Headache; Immune Thrombocytopenia; Insomnia; Ischaemic Stroke; Malaise; Mastication Disorder; Nausea; Pain; Platelet Count Decreased; Pulmonary Hypertension; Weight Decreased	Sildenafil Citrate			S		Unk		Pfizer
	Ambrisentan			S		10 Mg, Daily (10 Mg, 1d)		Not Reported
	Ambrisentan			S				Not Reported
	Furosemide			S		Unk		Not Reported
	Paracetamol			S		Unk		Not Reported
	Puran T4			S		Unk		Not Reported
	Marevan			S		Unk		Not Reported
	Reuquinol			S		Unk		Not Reported
	Volibris			S		10 Mg, Daily		Not Reported
	Cardizem [Diltiazem Hydrochloride]			C		Unk		Not Reported
	Bosentan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18101366	EXPEDITED (15-DAY)		OT	CA-ACCORD-193737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate	S	Unknown	Not Specified	Accord
	Orencia	S	Unknown		Not Reported
	Actemra	S	Unknown	Not Specified	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Meloxicam	C	Unknown	Not Specified	Not Reported
	Sulfasalazine	C	Unknown	Not Specified	Not Reported
	Leflunomide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18115948	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1068833		69 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Off Label Use; Transaminases Increased	Azithromycin			S	Oral	500 Milligram, Qd(500mg/Dia)		Mylan
	Plaquinol			S	Oral	400 Milliequivalent, Qd(400mg De 12/12h Em D0 E Depois 200mg 12/12h)		Mylan
	Metoclopramide			C	Oral	10 Milligram, Prn		Mylan
	Allopurinol			C	Oral	100 Milligram, Qd (24/24h)		Mylan
	Cetirizine			C	Oral	10 Milligram, Qd		Mylan
	Amoxicillin Clavulanic Acid			C	Oral	2 Dosage Form, Qd(8/8h)		Mylan
	Piperacillin And Tazobactam			C		2 Dosage Form, Qd (1 Cp		Mylan

				8h/8h)	
	Metamizole Magnesium	C	Oral	575 Milligram, Prn (Sos)	Mylan
	Alfuzosin	C	Oral	10 Milligram, Qd (1 Cp 1xdia)	Mylan
	Paracetamol	C	Oral	1000 Milligram, Prn(Sos)	Mylan
	Atenolol	C	Oral	50 Milligram, Qd(1 Cp 24/24h)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18129140	EXPEDITED (15-DAY)		HO	CA-ACCORD-194563			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Gamastan			S	Intravenous (not otherwise specified)	Dosage Form:Liquid Intramuscular		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

	Triamcinolone	C	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Specified	Not Reported
	Methotrexate	S	Subcutaneous		Accord
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral	Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18159354	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2020-04758		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder; Infection; Multiple Organ Dysfunction Syndrome; Oesophageal Motility Disorder; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Hydroxychloroquine			S				Lupin
	Cyclosporine			S	Unknown	175 Milligram, Bid		Not Reported
	Cyclosporine			S				Not Reported
	Prednisone			S	Unknown	15 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	20 Milligram, Qd		Not Reported
	Pyridostigmine			C	Unknown	60 Milligram, Qid		Not Reported
	Immunoglobulins Nos			C	Unknown	2 Gram Per Kilogram		Not Reported
	Immunoglobulins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18159665	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-038			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Furosemide			S	Unknown	Unknown		Westward

	Hydroxychloroquine	S	Unknown	Unknown		Not Reported
	Azithromycin	S	Unknown	Unknown		Not Reported
	Meropenem	S	Unknown	Unknown		Not Reported
	Piperacilin/Tazobactam	S	Unknown	Unknown		Not Reported
	Heparin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160008	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010326		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hand Deformity; Hepatic Fibrosis; Joint Dislocation; Non-Alcoholic Steatohepatitis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Methotrexate Pharmascience			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160176	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202008007753			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Neuroma; Pollakiuria; Rash; Rash Pruritic; Urticaria	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Nexium Mups			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160224	EXPEDITED (15-DAY)		OT	CA-ACCORD-195463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate			S	Oral			Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	C	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160328	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04681		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Colchicine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160440	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04742		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160626	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1815107		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain;	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Penicillamine	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Amitriptyline Hydrochloride	C	Unknown			Not Reported
	Doxycycline	C	Unknown			Not Reported
	Elavil	C				Not Reported
	Prednisone	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Tobramycin	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160630	EXPEDITED (15-DAY)		OT	JP-LUPIN PHARMACEUTICALS INC.-2020-04795		36 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Hydrocortisone			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160655	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-257921		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Hydroxychloroquine			S	Unknown	Unk		Sun
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Amoxicillin			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160747	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04640		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Hydrocortisone Butyrate			S	Unknown	100 Milligram, Bid		Lupin
	Hydrocortisone Butyrate			S	Unknown	100 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160775	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04753		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydrocortisone			S	Intravenous (not otherwise specified)	100 Milligram (Stress Dose)		Lupin
	Hydroxychloroquine			S		200 Milligram		Lupin
	Epinephrine			C	Intravenous (not otherwise specified)	0.4 Microgram/Kilogram Per Minute		Not Reported
	Milrinone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18160912	EXPEDITED (15-DAY)		OT	KR-LUPIN PHARMACEUTICALS INC.-2020-04696		78 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Levofloxacin			S	Unknown	Unk		Lupin
	Levofloxacin			S	Unknown	750 Milligram, Qd		Lupin

Vancomycin	S	Unknown	1 Gram, Bid		Lupin
Methylprednisolone	S	Unknown	0.5 Milligram/Kilogram		Lupin
Methylprednisolone	S	Unknown	1 Milligram/Kilogram (Injection)		Lupin
Kaletra	C	Oral	2 Dosage Form, Bid		Not Reported
Piperacillin + Tazobactam	C	Unknown	Unk		Not Reported
Meropenem	C	Unknown	1 Gram, Tid		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18161377	NON-EXPEDITED			US-ADVANZ PHARMA-202008007840			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased	Hydroxychloroquine			S		Unk		Concordia
	Methotrexate			S		Unk		Not Reported
	Xeljanz/Xeljanzxr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18161416	EXPEDITED (15-DAY)		OT	NVSC2020US225805		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Product Use In Unapproved Indication; Retinopathy	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	300 Mg, Unknown		Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Bid 8.2 Mg/Kg Actual Body Weight Per Day		Novartis
	Prednisone			C	Unknown			Not Reported
	Mycophenolate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162041	DIRECT	Y	HO			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Haemolytic Anaemia; Liver Disorder; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Hydroxychloroquine			S	Oral			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162370	EXPEDITED (15-DAY)		DE	CA-ACCORD-195091		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Atorvastatin/Atorvastatin Calcium			S		1 Every 1 Days		Not Reported
	Alendronate Sodium/Alendronic Acid			S		1 Every 1 Weeks		Accord
	Furosemide			S		1 Every 1 Days		Accord
	Tylenol			S		1 Every 1 Days		Not Reported
	Salmeterol			S				Not Reported
	Prednisone			S		1 Every 1 Days		Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Nitrazepam			S		1 Every 1 Days		Not Reported
	Metformin			S	Oral	2 Every 1 Days		Not Reported
	Losec			S	Oral	1 Every 1 Days		Not Reported
	Lipitor			S		1 Every 1 Days		Not Reported
	Ipratropium/Salbutamol			S				Not Reported
	Flovent			S				Not Reported
	Atrovent			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162383	EXPEDITED (15-DAY)		OT	CA-ACCORD-195447		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered;	Methotrexate			S	Oral	1 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Simponi	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Reactine [Cetirizine]	S	Unknown		Not Reported
	Pseudoephedrine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Plaquenil	S	Unknown	1 Every 1 Days	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Fosamax	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Cortisone	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Every 1 Days	Not Reported
	Methotrexate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162530	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-25536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Sublingual	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162877	EXPEDITED (15-DAY)		HO, OT	TR-APPCO PHARMA LLC-2088731		65 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162894	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202008007788			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Feeling Hot; Oedema Mucosal; Rash; Skin Disorder; Skin Mass	Hydroxychloroquine		S	Unknown	200 Mg		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162906	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-065104		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Calcium Carbonate/Vitamin D3			C	Unknown	Unk		Not Reported
	Hydrocortisone			C	Unknown	Unk Unk, Bid		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	20 Milligram, Qd		Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown	2 Dosage Form, Bid		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162925	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-257182		34 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukopenia;	Hydroxychloroquine			S	Unknown	Unk		Sun

Off Label Use; Serum Ferritin Increased	Lopinavir/Ritonavir			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163436	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012422		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S				Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	12.5 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Sulfasalazine		C	Unknown	1 G, Bid	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163593	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1072466			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cardiomegaly; End Stage Renal Disease; Maculopathy; Prescribed Overdose; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	300 Milligram, Qd, 6.5mg/Kg Per Day		Mylan
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd, 8.2mg/Kg Per Day		Mylan
	Prednisone			C	Unknown			Mylan
	Mycophenolate			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163711	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009083		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported
	Remicade			S	Unknown	300 Mg, Unk (Once In 6 Weeks)		Not Reported
	Rituxan			S	Unknown	1000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	2000 Mg, Unk (Once In 6 Months)		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk		Not Reported
Methotrexate	C	Oral	10 Mg, Q.Wk.		Not Reported
Prednisone	C	Oral	10 Mg, Qd		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported
Gold	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163856	EXPEDITED (15-DAY)		HO, LT	RO-MYLANLABS-2020M1071594		35 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Haemoptysis; Off Label Use; Vomiting	Lopinavir/Ritonavir			S		Unk		Mylan
	Azithromycin Dihydrate			S		Unk		Mylan
	Tocilizumab			S		800 Mg, 3 Administrations		Mylan
	Dexamethasone			S		16 Milligram, Qd (16 Mg, Per Day)		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Meropenem			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164305	EXPEDITED (15-DAY)		HO	NVSC2020FR221675		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jugular Vein Thrombosis; Pneumonia Bacterial; Staphylococcal Bacteraemia; Staphylococcal Bacteraemia; Staphylococcal Infection; Thrombosis	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Sarilumab			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Sarilumab			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

Tazocilline	C	Unknown	Unk		Not Reported
Heparine	C	Unknown	Unk		Not Reported
Lansoprazole	C	Unknown	Unk		Not Reported
Lasilix	C	Unknown	Unk		Not Reported
Diprivan	C	Unknown	Unk		Not Reported
Noradrenaline	C	Unknown	Unk		Not Reported
Hypnovel	C	Unknown	Unk		Not Reported
Novorapid	C	Unknown	Unk		Not Reported
Tracrium	C	Unknown	Unk		Not Reported
Umuline	C	Unknown	Unk		Not Reported
Sufenta	C	Unknown	Unk		Not Reported
Amiklin	C	Unknown			Not Reported
Lantus	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164340	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020317223			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Skin Cancer; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Plaquenil			S	Unknown	200 Mg		Not Reported
	Xeljanz			C	Unknown	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18165636	EXPEDITED (15-DAY)		DE, HO, OT	IR-IPCA LABORATORIES LIMITED-IPC-2020-IR-002740			Unknown	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Condition	Hydroxychloroquine			S	Unknown	Unk		Ipca

Aggravated; Heart Injury; Hypotension; Maternal Exposure During Pregnancy; Myocarditis	Azithromycin		S	Unknown	Unk	Not Reported
	Ceftriaxone		S	Unknown	Unk	Not Reported
	Oseltamivir		S	Oral	Unk	Not Reported
	Kaletra		S	Unknown	Unk	Not Reported
	Fentanyl		S	Unknown	Unk	Not Reported
	Propofol		S	Unknown	Unk	Not Reported
	Cisatracurium		S	Unknown	Unk	Not Reported
	Vancomycin		S	Unknown	Unk	Not Reported
	Meropenem		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18168294	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-25540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Live Birth;	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Apo Prednison			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral	Unknown		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Diethylamine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Paracetamol	S	Unknown	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Subcutaneous	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Salazopyrine	S	Oral		Not Reported
	Sarilumab	S	Unknown	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Stelera	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported

Sulfasalazine	S	Oral			Not Reported
Tocilizumab	S	Subcutaneous	Unknown		Not Reported
Topicort	S	Subcutaneous	Unknown		Not Reported
Topicort	S	Oral	Unknown		Not Reported
Winpred	S	Oral	Unknown		Not Reported
Xeljanz	S	Unknown	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18169265	EXPEDITED (15-DAY)		DE, HO, OT	EG-ROCHE-2658856		41 YR	Male	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Respiratory Distress Syndrome; Death; Delirium; Hallucination; Nightmare; Off Label Use; Oral Candidiasis; Pneumocystis Jirovecii Pneumonia; Product Use In Unapproved Indication; Product Use Issue	Actemra			S	Unknown	Frequency: 3 Consecutive Doses Every 12 Hrs. Then The 4th After Being Ventilated.		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Clexane			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Lactoferrin			S	Unknown			Not Reported
	Zinc			S	Unknown			Not Reported
	Vitamin C			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Aluvia			S	Oral	Frequency: 2 Tab./12 Hrs. For 12 Days		Not Reported
	Hydroxychloroquine			S	Unknown	Frequency: 400mg/12 Hrs For 1 Day		Not Reported
	Hydroxychloroquine			S	Unknown	Frequency: 400mg/12 Hrs For 1 Day Then 200mg/12 Hrs For The Next Days.		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18169341	EXPEDITED (15-DAY)		DS, LT	CA-ROCHE-2658846		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 0.0		Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous	Therapy Duration: 365.0	Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Plaquenil	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Canada)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 365.0	Not Reported
Sulfasalazine	S	Oral		Not Reported
Tofacitinib	S	Unknown	Therapy Duration: 365.0	Not Reported
Topicort (Canada)	S	Unknown		Not Reported
Topicort (Canada)	S	Cutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported
Actemra	S	Subcutaneous		Not Reported
Salazopyrina	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18169360	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020317245			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Dactylitis; Drug Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Methotrexate Sodium		S	Subcutaneous	25 Mg, Weekly	Pfizer
	Azathioprine		S	Unknown	Unk	Not Reported
	Cosentyx		S	Unknown	300 Mg, Monthly	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, 1x/Day	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Prednisone		C	Oral	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	13006742	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015239		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain;	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Alendronate			S				Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, Q.Wk.		Not Reported

Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.O.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, 1 Every 4 Weeks	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, One Every Four Weeks	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, One Every Four Weeks	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, One Every Four Weeks	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, One Every Four Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported

Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	760 Mg, Q.Wk.	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unspecified Unit)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Bid	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported

Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Q.Wk.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	360 Mg, Q.M.T.	Not Reported
Simponi	S	Subcutaneous	680 Mg, Q.M.T.	Not Reported
Etanercept	S	Unknown	50 Mg, Q.Wk.	Not Reported
Etanercept	S	Unknown	25 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported
Prednisone	C	Unknown	10 Mg, Qd	Not Reported
Prednisone	C	Unknown	10 Mg, Qd	Not Reported
Prednisone	C	Unknown	10 Mg, Q.2h.	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

Xeljanz	C	Unknown	5 Mg, Bid		Not Reported
Alendronate Sodium	C	Subcutaneous	70 Mg, Q.Wk.		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Prednisolone	C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	13059209	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015767			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, 411 Unspecified Unit		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	13059562	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015791		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis; Vasculitic Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Q.Wk.		Apotex
	Leflunomide			S	Oral	20 Mg, Q.Wk.		Apotex
	Leflunomide			S	Oral	12.5 Mg, Q.O.Wk.		Apotex
	Leflunomide			S	Unknown	20 Milligram, Q.O.Wk.		Apotex
	Leflunomide			S	Oral	20 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Q.Wk.		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.,		Not Reported
	Humira			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported

Humira	S	Subcutaneous	40 Mg, Q.O.Wk.,	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Oral	12.5 Mg, Qd	Not Reported
Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Oral	12.5 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Oral	12.5 Mg, Qd	Not Reported
Methotrexate	S	Oral	12.5 Unk	Not Reported
Methotrexate	S	Unknown	Unk, Q.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk, Once Every 4 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	500 Mg, Cyclical	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclical	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q.M.T.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Milligram, 1 Every Four Months	Not Reported
Kineret	S	Subcutaneous	100 Mg, Qd	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Q.Wk.	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk, Bid	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	13251617	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006643			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	10 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milliliter, Bid		Not Reported
	Desoximetasone			C	Subcutaneous	Unk		Not Reported

Diclofenac	C	Oral	5 Milligram, Bid		Not Reported
Diclofenac	C	Unknown	100 Milligram, Qd		Not Reported
Diclofenac	C	Unknown	100 Milligram		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Desoximetasone	C	Oral	5 Milligram, Bid		Not Reported
Desoximetasone	C	Oral	10 Milligram, Qd		Not Reported
Desoximetasone	C	Oral	Unk		Not Reported
Diclofenac	C	Subcutaneous	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	13939230	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017490		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Off Label Use; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Apo-Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Prolia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	13962979	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017777		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk, Prn		Not Reported
	Pregabalin			C	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	13965420	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017881		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Celebrex			S	Oral	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	1 Ml, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Mg, 1 Eveery 1 Weeks		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported
	Humira			S	Unknown	40 Unk, Cyclical		Not Reported
	Humira			S	Unknown	50 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Unknown	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	50 Milligram, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Unk		Not Reported

Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Unknown	25 Mg, 1 Every 2 Weeks	Not Reported
Methotrexate Sodium	S	Unknown	5 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Unknown	7.5 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Unknown	10 Mg, 1 Every 2 Weeks	Not Reported
Methotrexate Sodium	S	Unknown	5 Mg, 1 Every 2 Weeks	Not Reported
Methotrexate Sodium	S	Unknown	7.5 Mg, 1 Every 2 Weeks	Not Reported
Orencia	S	Unknown	125 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	12.5 Mg, 1 Every 2 Weeks	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Altace	C	Unknown	5 Mg, Unk	Not Reported
Altace	C	Unknown	10 Mg, Unk	Not Reported
Apo-Gabapentin	C	Oral	100 Mg, Unk	Not Reported
Apo-Gabapentin	C	Unknown	300 Mg, Unk	Not Reported
Apo-Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	C	Oral	15 Mg, Qd	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, Qd	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, 2 Every One Week	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, 1 Every 2 Week	Not Reported
Cipralex /01588501/	C	Unknown	10 Mg, Unk	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Mg, Unk	Not Reported
Citalopram Hydrobromide	C	Oral	Unk	Not Reported
Conjugated Estrogens	C	Oral	0.625 Mg, Unk	Not Reported
Cymbalta	C	Unknown	30 Mg, Qid	Not Reported
Cymbalta	C	Unknown	120 Mg, Qd	Not Reported
Cymbalta	C	Unknown	60 Mg, Unk	Not Reported
Escitalopram	C	Unknown	10 Mg, Unk	Not Reported
Estrace	C	Unknown	0.5 Mg, Unk	Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg, Unk	Not Reported

	Hydromorphone Hydrochloride	C	Oral	3 Mg, Bid	Not Reported
	Pantoloc /01263204/	C	Unknown	20 Mg, Qd	Not Reported
	Pantoloc /01263204/	C			Not Reported
	Ratio-Emtec	C	Unknown	Unk	Not Reported
	Shark Liver Oil	C	Unknown		Not Reported
	Tapentadol Hydrochloride	C	Unknown	50 Mg, Unk	Not Reported
	Taro-Mupirocin	C	Unknown	2 %, Unk	Not Reported
	Tramacet	C	Oral	Unk	Not Reported
	Tramadol	C	Oral	50 Mg, Unk	Not Reported
	Gabapentin	C	Oral	100 Mg, Unk	Not Reported
	Gabapentin	C	Unknown	300 Mg, Unk	Not Reported
	Prednisone	C	Oral	5 Mg, Unk	Not Reported
	Prednisone	C	Oral	5 Mg, Tid	Not Reported
	Prednisone	C	Unknown	15 Mg, Qd	Not Reported
	Mupirocin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	14235426	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021710			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	14746347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009094		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Orencia			S	Unknown	40 Mg/Kg, Q.O.Wk.		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	1 Df, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Mg, Qd	Not Reported
Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Mg, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300.0 Mg, Unk	Not Reported
Xeljanz	C	Unknown		Not Reported
Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported
Folic Acid	C	Oral	2.5 Mg, Qd	Not Reported
Folic Acid	C			Not Reported
Methotrexate	C	Oral	10 Milligram, Q.Wk.	Not Reported
Methotrexate	C	Oral	15 Milligram, Q.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	14921412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044420		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; Vomiting	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	75 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	2.0 Dosage Form, Qd		Not Reported

Hydroxychloroquine	S	Oral	10.0 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	5.0 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	2 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	10 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram, 1 Every 2 Weeks	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	40 Milligram, 1 Every 2 Weeks	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Cyclosporine	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	10 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported

Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Ciclosporin	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
Arava	C	Oral	1 Dosage Form, Qd		Not Reported
Risedronate	C	Oral	35 Milligram, Qwk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	2 Dosage Form, Qd		Not Reported
Rituximab	S	Oral	Unk		Not Reported
Xeljanz Xr	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Unknown	2 Dosage Form, Qd		Not Reported
Xeljanz	C	Oral	10 Milligram, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	15712231	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US052428		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Azathioprine			S	Unknown	Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk, Unknown Freq.		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported

	Gold	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	16537815	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017574		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Azathioprine			S	Unknown	Unk		Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Apotex
	Hydroxychloroquine			S	Oral	400 Milligram, Q.Wk.		Apotex
	Pregabalin			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram		Apotex
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	64 Milligram, Q.Wk.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Once Every 4 Weeks		Not Reported
	Azathioprine			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Azathioprine			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Q.Wk.		Not Reported

Certolizumab Pegol	S	Unknown	200 Milligram, Q.O.Wk.	Not Reported
Certolizumab Pegol	S	Subcutaneous	200 Milligram, Q.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Q.Wk.	Not Reported
Imuran /00001501/	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Q.Wk.	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported

Varicella Zoster Vaccine Live	S	Subcutaneous	Unk		Not Reported
Tocilizumab	S	Unknown	640 Milligram, Q.Wk.		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Piroxicam	C	Unknown	Unk		Not Reported
Prednisone	C	Oral	Unk		Not Reported
Folic Acid	C	Unknown	5 Milligram		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	17240411	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026873		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported

	Cimzia	C	Unknown	Unk		Not Reported
	Enbrel	C	Unknown	Unk		Not Reported
	Humira	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Varenicline Tartrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	17837485	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526864		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Ulcer	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular	Also Reported As Route Of Administration As Parenteral	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	17844865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Cosentyx	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Etanercept	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Calcium Gluconate	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Quetiapine	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	17846174	EXPEDITED (15-DAY)		OT	AU-ROCHE-2611142			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Graft Versus Host Disease In Skin	Mabthera			S	Unknown	Drug Withdrawn		Not Reported

	Ciclosporin	S	Unknown	Drug Withdrawn	Not Reported
	Ibrutinib	S	Unknown	Drug Withdrawn	Not Reported
	Prednisolone	S	Unknown	Dose Not Changed	Not Reported
	Sirolimus	S	Unknown	Dose Not Changed	Not Reported
	Hydroxychloroquine	S	Unknown	Dose Not Changed	Not Reported
	Lamotrigine	C			Not Reported
	Quetiapine	C			Not Reported
	Bactrim Ds	C			Not Reported
	Valaciclovir	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	17907320	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1055892		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Bisoprolol			S		Unk		Mylan
	Amiodarone			S		Unk		Mylan
	Spiramycin			S		Unk		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	600 Mg, Qd		Mylan
	Sarilumab			S	Subcutaneous	400 Milligram, Total (400 Mg, 1x)		Mylan
	Hydroxyzine			C		Unk		Mylan
	Monoprost			C		Unk		Mylan
	Gabapentine			C		Unk		Mylan
	Insulin			C		Unk		Mylan
	Enoxaparin			C		Unk		Mylan
	Lansoprazole			C		Unk		Mylan
	Eplerenone			C		Unk		Mylan
	Tamsulosine /01280301/			C		Unk		Mylan
	Clopidogrel			C		Unk		Mylan
	Oxazepam			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	17954128	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-251570		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyshidrotic Eczema; Eczema; Off Label Use; Pruritus	Azithromycin			S	Oral	500 Milligram, Daily, Tablet		Sun
	Plaquenil			S	Oral	2 Dosage Form, Daily		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	1 Dosage Form, Daily		Not Reported
	Kaletra 200 Mg/50 Mg Film-Coated Tablets			S	Oral	2 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18101250	EXPEDITED (15-DAY)		OT	CA-ACCORD-193590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Oral	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Prednisone			C	Unknown	Not Specified		Not Reported

	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18133609	EXPEDITED (15-DAY)		DE, HO, LT	CA-ACCORD-194536			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S		Single-Use Vial, Powder For Solution Subcutaneous		Not Reported
	Leflunomide			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial,		Not Reported
	Ilaris			S		Single-Use Vial,		Not Reported
	Leflunomide			S				Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18156827	EXPEDITED (15-DAY)		DE, OT	TR-PFIZER INC-2020313417		35 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Maternal Exposure During Pregnancy; Off Label Use	Azithromycin	S	Oral	500 Mg	Pfizer
	Azithromycin	S			Pfizer
	Methylprednisolone Acetate	S	Intramuscular	40 Mg	Pfizer
	Methylprednisolone Acetate	S			Pfizer
	Favipiravir	S	Oral	200 Mg	Not Reported
	Favipiravir	S			Not Reported
	Favipiravir	S			Not Reported
	Enfluvir	S	Oral	75 Mg	Not Reported
	Enfluvir	S			Not Reported
	Enfluvir	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	1 G	Not Reported
	Ceftriaxone	S			Not Reported
	Ceftriaxone	S			Not Reported
	Piperacillin	S	Intravenous (not otherwise specified)	4.5 G	Not Reported
	Piperacillin	S			Not Reported
	Piperacillin	S			Not Reported
	Enoxaparin	S	Subcutaneous	Unk (0.6)	Not Reported
	Enoxaparin	S			Not Reported
	Enoxaparin	S			Not Reported
	Insulin	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18165118	EXPEDITED (15-DAY)		OT	CA-ACCORD-195438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Lupus Erythematosus	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18165120	EXPEDITED (15-DAY)		HO	CA-ACCORD-195437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Alendronate Sodium/Alendronic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown	1 Every 1 Months		Not Reported
	Codeine			S	Unknown			Not Reported

Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Skin Ulcer	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown	1 Every 1 Days	Not Reported
	Prednisone	C	Unknown	1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18165122	EXPEDITED (15-DAY)		HO	CA-ACCORD-195440		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion	Methotrexate			S	Unknown	1 Every 4 Weeks		Accord
	Alendronate Sodium/Alendronic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown	1 Every 1 Months		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Parenteral	1 Every 1 Months		Not Reported
	Orencia			S	Unknown	1 Every 1 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Rituximab	S	Intravenous drip	2 Every 1 Days	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	1 Every 4 Weeks	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	1 Every 1 Days	Not Reported
	Prednisone	C	Unknown	1 Every 1 Days	Not Reported
	Actemra	S	Unknown	1 Every 1 Months	Not Reported
	Enbrel	S	Unknown	1 Every 1 Weeks	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 1weeks	Accord
	Methotrexate	S	Oral	1 Every 4 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 4 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 4 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 4 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 4 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 4 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 4 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 4 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 4 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 4 Weeks	Accord
	Rituximab	S	Unknown	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18165419	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Infection; Leukopenia; Lymphopenia; Rash;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Serum Ferritin Increased; Systemic Lupus Erythematosus; Transient Ischaemic Attack; Treatment Failure				otherwise specified)	
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Atorvastatin Calcium		C	Unknown	Not Reported
	Bisoprolol		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Furosemide		C	Unknown	Not Reported
	Mycophenolate Sodium		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Ramipril		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18165628	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04723		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk		Lupin
	Zinc			C	Unknown	Unk		Not Reported
	Guaifenesin			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Meropenem			C	Unknown	Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported
	Atrovent			C	Unknown	Unk		Not Reported
	Mucomyst [Acetylcysteine]			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Actemra			C	Unknown	500 Milligram, Qd (At Night Of Day 1)		Not Reported
	Actemra			C	Unknown	500 Milligram, Qd (In Morning)		Not Reported

	Albuterol [Salbutamol]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18165652	EXPEDITED (15-DAY)		OT	KR-LUPIN PHARMACEUTICALS INC.-2020-04791		73 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydrocortisone			S	Unknown	200 Milligram, Qd		Lupin
	Hydrocortisone			S				Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18166150	NON-EXPEDITED			US-ADVANZ PHARMA-202008007806			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S		Unk (Plaquenil)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18166174	EXPEDITED (15-DAY)		OT	CA-ACCORD-195428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18166379	EXPEDITED (15-DAY)		OT	CA-ACCORD-195942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18166428	EXPEDITED (15-DAY)		HO, OT	IR-VISTAPHARM, INC.-VER202008-001385		15 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Posterior Reversible Encephalopathy Syndrome	Prednisolone	S		70 Mg Daily	Vistapharm
	Cyclophosphamide	S		500 Mg (Pulse Therapy)	Not Reported
	Cyclophosphamide	S		500 Mg (Second Pulse Therapy)	Not Reported
	Hydroxycholoroquine Sulphate-Bp	S		200 Mg Daily	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	1 G	Not Reported
	Phenytoin	C		Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18166636	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-04798			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Apgar Score Low; Apnoea; Cyanosis; Foetal Exposure During Pregnancy; Foetal Heart Rate Abnormal; Intraventricular Haemorrhage; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Azithromycin			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Magnesium Sulfate			C	Transplacental	Unk		Not Reported
	Remdesivir			C	Transplacental	Unk		Not Reported
	Tocilizumab			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18166638	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-04687		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin

	Magnesium Sulfate	C	Unknown	Unk		Not Reported
	Remdesivir	C	Unknown	Unk		Not Reported
	Tocilizumab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18167539	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1815875		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18167549	EXPEDITED (15-DAY)		OT	PL-TEVA-2020-PL-1814988		65 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Haemolytic Anaemia; Off Label Use	Methotrexate			S	Unknown			Barr
	Dapsone			S	Unknown	100 Milligram Daily;		Not Reported
	Prednisone			S	Oral	40 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported

	Doxycycline		S	Unknown	100 Milligram Daily;	Not Reported
	Mepolizumab		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18167934	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-196260			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			C		1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168108	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1814956		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168180	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04691		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168388	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-257292		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Off Label Use	Hydroxychloroquine			S	Oral			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168415	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04899		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Vitamin C [Ascorbic Acid]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168781	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04898		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Vitamin C [Ascorbic Acid]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169785	EXPEDITED (15-DAY)		OT	CA-ACCORD-195430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169786	EXPEDITED (15-DAY)		OT	CA-ACCORD-195426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169787	EXPEDITED (15-DAY)		OT	CA-ACCORD-195431			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand	Methotrexate			S	Intra-arterial	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown	1 Every 1 Days		Not Reported

Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Cortisone	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe	Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate	S	Unknown	1 Every 1 Days	Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

	Sulfasalazine			S	Unknown	2 Every 1 Days				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169789	EXPEDITED (15-DAY)		OT	CA-ACCORD-195433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Alendronate Sodium/Alendronic Acid			S	Unknown			Accord
	Actemra			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169824	EXPEDITED (15-DAY)		OT	CA-ACCORD-195944		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate	S	Oral	Accord
	Sulfasalazine	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Leflunomide	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Leflunomide	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported
	Neoral	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Accord
	Hydroxychloroquine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169829	EXPEDITED (15-DAY)		OT	CA-ACCORD-195945			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate			S	Oral			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported

	Prednisone	S	1 Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169873	EXPEDITED (15-DAY)		OT	CA-ACCORD-195650			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Methotrexate			S				Accord
	Metformin			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Colchicine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Januvia			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169882	EXPEDITED (15-DAY)		OT	CA-ACCORD-196021		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use Issue	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Immunoglobulin G Human			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Immunoglobulin G Human			C	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169884	EXPEDITED (15-DAY)		HO	CA-ACCORD-196088		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169898	EXPEDITED (15-DAY)		OT	DE-SA-2020SA215495			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pain In Extremity; Subclavian Vein Thrombosis; Swelling	Quensyl			S		Unk		Sanofi
	Lantus			S		Unk		Sanofi
	Apidra			S		Unk		Sanofi
	Levosert			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169953	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169976	NON-EXPEDITED			US-AMGEN-USASP2020133497			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Weekly		Amgen
	Adalimumab			S	Unknown	40 Mg, Qwk		Amgen
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Xeljanz Xr			C	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18170002	EXPEDITED (15-DAY)		OT	CA-ACCORD-195739			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Atorvastatin/Atorvastatin			S	Oral	1 Every 1 Days		Not Reported
	Calcium							
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Paracetamol			C	Oral			Not Reported
	Folic Acid			C	Oral	1 Every 1 Weeks		Not Reported
	Sns-Asa Ec			C	Oral	1 Every 1 Days		Not Reported
	Colecalciferol			C	Oral			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18170019	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS		69 YR	Female	USA

INC.-2020-04762

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18170021	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04724		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18170027	EXPEDITED (15-DAY)		OT	CA-ACCORD-196296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral	1 Every 1 Days		Accord
	Actemra			S				Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Leflunomide			C				Not Reported

	Folic Acid		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18170164	EXPEDITED (15-DAY)		DE	US-MYLANLABS-2020M1072471		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Haematuria; Nephropathy Toxic; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd, 4.2mg/Kg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18172088	EXPEDITED (15-DAY)		LT	NVSC2020US229051		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18173270	EXPEDITED (15-DAY)		OT	CA-FRESENIUS KABI-FK202008432		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue;	Folic Acid (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Paracetamol			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Chlorhexidine	S	Topical	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Cortisone	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Paracetamol/Oxycodone	S	Unknown	Not Reported

Hydrochloride Chlorhexidine Gluconate	S	Buccal	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Golimumab	S	Subcutaneous	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Phthalylsulfathiazole	S	Oral	Not Reported
Phthalylsulfathiazole	S	Oral	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Ethinylestradiol/Desogestrel	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Codeine Phosphate/Paracetamol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	13059166	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015754		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	13059788	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2016AP015748		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism;	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S				Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Enbrel	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Intra-arterial	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Urelumab	C	Unknown	Unk	Not Reported
	Ilaris	C	Subcutaneous		Not Reported
	Ilaris	C			Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Methotrexate	C	Intra-arterial	Unk	Not Reported
	Anakinra	C	Unknown	Unk	Not Reported

Hydroxychloroquine	C	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	13250481	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006555		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Latent Tuberculosis; Rash; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Endocervical	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.I.W		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	13854282	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070658			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise;	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form		Not Reported

Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Cimzia	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Advil [Mefenamic Acid]	C	Unknown		Not Reported
	Prednisone	C	Oral	6 Milligram, Qd	Not Reported
	Prednisone	C	Oral	10 Milligram, Qd	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Dequalinium Chloride	C	Unknown	Unk	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	14752378	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2018AP009554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	14921972	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported

Treatment Failure	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Apo Mycophenolate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Unknown	25 Milligram, Qd	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	25 Milligram, 1 Every 24hours	Not Reported
	Morphine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	15330288	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019418		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Swelling	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Naproxen Sodium			S	Unknown	Unk, Bid		Apotex
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	15333883	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019373		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous	200 Mg, One Every Two Weeks		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	200 Milligram, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, One Every Two Weeks		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	15621514	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557370-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Irritable Bowel Syndrome; Joint Swelling; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	16085215	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06150		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure	Infliximab			S	Unknown	Unknown		Not Reported

Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Etanercept	S	Unknown	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Acetaminophen	C	Oral	Unknown	Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	Unknown,Ointment	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Unknown	Not Reported

	Ferrous Gluconate	C	Unknown	Unknown	Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported
	Lasix	C	Unknown	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Unknown	Not Reported
	Naprosyn	C	Unknown	Unknown	Not Reported
	Oxycontin	C	Unknown	Unknown	Not Reported
	Oxycontin	C	Unknown	Unknown, Extended Release	Not Reported
	Oxyneo	C	Unknown	Unknown	Not Reported
	Oxyneo	C	Unknown	Unknown, Extended Release	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	17591358	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009095		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	17703402	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020221		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pulmonary Embolism	Paracetamol		S	Oral	4 Gram, Once A Day	Aurobindo
	Amlor		S	Oral	1 Dosage Form, Once A Day	Not Reported
	Arimidex		S	Oral	1 Milligram, Once A Day	Not Reported
	Augmentin		S	Intravenous (not otherwise specified)	3 Gram, Once A Day	Not Reported
	Colchimax (Colchicine/Papaver Somniferum Powder/Tiemonium Methylsulphate)		S	Oral	1 Dosage Form, Once A Day	Not Reported
	Nefopam Hydrochloride		S	Oral	80 Milligram, Once A Day	Not Reported
	Plaquenil		S	Oral	400 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	17712539	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010162		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Condition Aggravated; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal	Folic Acid			S	Oral	5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Calcium Folinate			S	Oral	5 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Discomfort; Nasopharyngitis; Nausea; Night Sweats; Off Label Use; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Acetaminophen	C	Oral	Unk	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Fentanyl	C	Unknown	1 Df, Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, Bid	Not Reported
	Metformin Hydrochloride W/Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Perindopril Erbumine	C	Oral	8 Mg, Qd	Not Reported
	Rabeprazole	C	Oral	180 Mg, Qd	Not Reported
	Ranitidine	C	Oral	150 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, Bid	Not Reported
	Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin B 12	C	Oral	1 Df, Qd	Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd	Not Reported
	Zostavax Ii	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	17763436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No	Rituximab			S	Intravenous drip			Not Reported

Adverse Event; Rheumatoid Arthritis	Sulfasalazine	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18025307	EXPEDITED (15-DAY)		OT	CA-ACCORD-190399		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral	2 Every 1 Weeks		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral	2 Every 1 Days		Not Reported
	Restasis			C	Oral			Not Reported
	Sulfasalazine			C	Oral	2 Every 1 Days		Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18027799	EXPEDITED (15-DAY)		OT	CA-ACCORD-190416			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	Not Specified		Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Azathioprine			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18047433	EXPEDITED (15-DAY)		LT	CA-ROCHE-2645823			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]				
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18068409	EXPEDITED (15-DAY)		OT	CA-ACCORD-191922		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Cannabis Sativa			C				Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate			C	Unknown			Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours Not Specified		Not Reported
	Xeljanz			C	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18123281	EXPEDITED (15-DAY)		OT	CA-ACCORD-194524		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	Accord
	Actemra	S	Unknown	Not Reported
	Alendronate Sodium/Alendronic Acid	S	Unknown	Accord
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Calcium Carbonate	S	Unknown	Not Reported
	Fosinopril	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Morphine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Synthroid	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Vitamin D	S	Unknown	Not Reported
	Paracetamol	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Morphine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18143853	EXPEDITED (15-DAY)		OT	CA-ACCORD-195011		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Bactrim			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous 2 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

					otherwise specified)	Intravenous				
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18146295	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1070245		71 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Aciclovir			S		Unk		Mylan
	Piperacillin			S		Unk		Not Reported
	Caspofungin			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Tazobactam			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18161190	EXPEDITED (15-DAY)		OT	BE-PFIZER INC-2020315949		50 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Norepinephrine Bitartrate			S		Unk, At Admission		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Heparin			S		Unk, At Admission		Not Reported
	Propofol			S		Unk, At Admission		Not Reported
	Clonidine			S		Unk, At Admission		Not Reported
	Sufentanil			S		Unk, At Admission		Not Reported
	Rocuronium Bromide			S		Unk, At Admission		Not Reported
	Pantoprazole			S		Unk, 9 Days Before		Not Reported
	Sevoflurane			S		Unk, 8 Days Before		Not Reported
	Cefuroxime			S		Unk, 6 Days Before		Not Reported
	Flucloxacillin Sodium			S		Unk, 4 Days Before		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18163019	EXPEDITED (15-DAY)		HO, OT	IL-TEVA-2020-IL-1815038		68 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Drug Ineffective; Epidermal Necrosis; Lupus-Like Syndrome; Rash; Urticaria	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Etanercept			S	Unknown	Once A Week		Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Famotidine			C	Unknown			Not Reported
	Brotizolam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172106	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04792		54 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk, Boluses		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Tocilizumab			C	Unknown	600 Milligram, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172293	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-195928			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Enbrel			S				Not Reported

Product Use Issue; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172298	EXPEDITED (15-DAY)		HO	CA-ACCORD-196163			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172303	EXPEDITED (15-DAY)		OT	CA-ACCORD-195930		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered	Methotrexate			S		1 Every 1 Weeks		Accord
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S				Not Reported
	Arava			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Prednisone			C	Oral			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172316	EXPEDITED (15-DAY)		OT	LU-AUROBINDO-AUR-APL-2020-039528		69 YR	Male	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Bisoprolol			S	Oral	1.25 Milligram, Once A Day		Aurobindo
	Dipidolor			S	Intravenous drip	1 Milligram, Every Hour		Not Reported
	Dipidolor			S	Intravenous drip	1 Milligram, Every Hour		Not Reported
	Sufenta			S	Intravenous drip	10 Microgram, Every Hour		Not Reported
	Sufenta			S	Intravenous drip	15 Microgram, Every Hour		Not Reported
	Propofol-Lipuro 1%			S	Intravenous drip	10 Milligram, Every Hour		Not Reported
	Propofol-Lipuro 1%			S	Intravenous drip	20 Mg, 1 Total (Before Care)		Not Reported

Kaletra	S	Oral	5 Milliliter, Two Times A Day	Not Reported
Erythrocin	S	Intravenous (not otherwise specified)	125 Milligram, Four Times/Day	Not Reported
Lysomucil	S	Intravenous (not otherwise specified)	300 Milligram, Four Times/Day	Not Reported
Plaquenil	S	Oral	400 Milligram, Two Times A Day	Not Reported
Plaquenil	S	Oral	200 Milligram, Two Times A Day	Not Reported
Nimbex	S	Intravenous drip	10 Milligram, Every Hour	Not Reported
Nimbex	S	Intravenous drip	10 Milligram, Every Hour	Not Reported
Levophed	S	Intravenous drip	6.8 Milligram, Every Hour	Not Reported
Levophed	S	Intravenous drip	6.8 Milligram, Every Hour	Not Reported
Propofol	S	Intravenous drip	200 Milligram, Every Hour	Not Reported
Catapressan	S	Intravenous drip	Unk (20 - 30 Microgramme/Hour)	Not Reported
Rydene	S	Intravenous (not otherwise specified)	Unk (2 - 5 Milligram Per Hour)	Not Reported
Lasix	C	Intravenous (not otherwise specified)	20 Milligram, Once A Day	Not Reported
Ceftriaxone Kabi	C	Intravenous (not otherwise specified)	2 Gram, Once A Day	Not Reported
Azactam	C	Intravenous (not otherwise specified)	2 Gram, 3 Times A Day	Not Reported
Midazolam B Braun	C	Intravenous drip	20 Milligram, Every Hour	Not Reported
Midazolam B Braun	C	Intravenous drip	20 Milligram, Every Hour	Not Reported
Glycophos	C	Oral	1 Dosage Form, Once A Day	Not Reported
Glycophos	C	Oral	1 Dosage Form, Once A Day	Not Reported
Movicol	C	Oral	1 Dosage Form, Once A Day	Not Reported

Nutrison Protein Plus Multi Fibre	C	Oral	10 Milliliter, Every Hour		Not Reported
Nutryelt	C	Oral	1 Dosage Form, Once A Day		Not Reported
Cernevit	C	Oral	1 Dosage Form, Once A Day		Not Reported
Vancomycine Kabi	C	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
Aspegic	C	Oral	100 Milligram, Once A Day		Not Reported
Actrapid	C	Intravenous (not otherwise specified)	1.5 International Unit, Every Hour		Not Reported
Paracetamol B Braun	C	Intravenous (not otherwise specified)	1 Gram, Four Times/Day		Not Reported
Euthyrox	C	Oral	150 Microgram, Once A Day		Not Reported
Clexane	C	Subcutaneous	80 Milligram, Two Times A Day		Not Reported
Piperacilline/Tazobactam Kabi	C	Intravenous (not otherwise specified)	4 Gram, Once A Day		Not Reported
Biclar	C	Intravenous (not otherwise specified)	500 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172505	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016277		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Diclofenac Sodium And Misoprostol			S	Oral	50 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.3w		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Q.Wk.		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported

	Sulfate]					
	Simponi	S	Subcutaneous	50 Milligram, Q.3w		Not Reported
	Sulfasalazine	S	Oral	2 Gram, Qd		Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172530	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1815808		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Teva Mycophenolate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Piroxicam			S	Unknown			Not Reported
	Pregabalin			S	Oral			Teva
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172610	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010391			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Skin Cancer; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172714	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2020-04901		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Nephropathy Toxic; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (4.2mg/Kg)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172741	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04902		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cardiomegaly; End Stage Renal Disease; Maculopathy; Prescribed Overdose; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	300 Milligram, Qd (6.5mg/Kg Per Day)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (8.2mg/Kg Per Day (200 Mg Twice Daily))		Lupin
	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172910	EXPEDITED (15-DAY)		OT	CA-ACCORD-196308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Methotrexate			S	Subcutaneous			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172911	EXPEDITED (15-DAY)		OT	CA-ACCORD-196354		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported

Therapy Partial Responder	Prednisone	S				Not Reported
	Rituximab	S				Not Reported
	Sulfasalazine	S		1 Every 2 Days		Not Reported
	Risedronic Acid	C				Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18172914	EXPEDITED (15-DAY)		OT	CA-ACCORD-196355			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Actemra			S				Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		1 Every 24 Hours		Not Reported
	Remicade			S		Powder For Intravenous Solution		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Paracetamol			C				Not Reported
	Caffeine/Caffeine Citrate			C				Not Reported
	Codeine			C				Not Reported
	Dorzolamide			C	Ophthalmic	2 Every 1 Days		Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Meprobamate			C				Not Reported
	Prednisone			C		1 Every 24 Hours		Not Reported
	Ramipril			C				Not Reported
	Timolol			C	Ophthalmic	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173005	EXPEDITED (15-DAY)		OT	CH-BIOVITRUM-2020CH4327		10 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coronary Artery	Anakinra	S		Not Reported
Aneurysm; Off Label Use;	Hydroxychloroquine	S		Not Reported
Renal Injury	Azithromycin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173090	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04741		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Vancomycin Hydrochloride			S	Unknown	Unk		Lupin
	Cefepime			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173101	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04692		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Cefpodoxime			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173103	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-04820		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delivery; Drug Ineffective; Exposure During Pregnancy; Hypocomplementaemia;	Methylprednisolone			S	Unknown	1 Gram, Unkn		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Lupin

Serositis; Synovitis; Vasculitis	Hydroxychloroquine		S	Oral	400 Milligram, Qd	Lupin
	Cyclophosphamide		S	Unknown	750 Milligram/Sq. Meter, Unk	Not Reported
	Cyclophosphamide		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone		S	Oral	60 Milligram, Qd	Not Reported
	Immunoglobulin I.V		S	Unknown	Unk	Not Reported
	Azathioprine		S	Unknown	Unk	Not Reported
	Lorazepam		C	Unknown	Unk	Not Reported
	Lorazepam		C	Unknown	8 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173105	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04909		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173349	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202008008004			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Gastritis; Peptic Ulcer; Sjogren'S Syndrome	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Paracetamol			C		Unk		Not Reported
	Etoricoxib			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173385	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-04940		65 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173393	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04877		13 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	Unk		Lupin
	Azithromycin			S	Oral	Unk		Lupin
	Digoxin			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Naproxen			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173469	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04783		33 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Darunavir			S	Oral	800 Milligram, Qd		Not Reported
	Paclitaxel			C	Unknown	Unk		Not Reported
	Paclitaxel			C				Not Reported
	Paclitaxel			C				Not Reported
	Ritonavir			C	Oral	100 Milligram, Qd		Not Reported
	Ifosfamide			C	Unknown	Unk		Not Reported
	Ifosfamide			C				Not Reported
	Ifosfamide			C				Not Reported
	Etoposide			C	Unknown	400 Milligram/Sq. Meter		Not Reported
	Etoposide			C				Not Reported
	Etoposide			C				Not Reported

Carboplatin	C	Unknown	Unk		Not Reported
Carboplatin	C				Not Reported
Carboplatin	C				Not Reported
Levofloxacin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173471	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04818		39 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	Unk		Lupin
	Lopinavir And Ritonavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173484	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04878		12 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173493	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05000		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Doxycycline			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173509	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04879		8 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	Unk		Lupin
	Oseltamivir			S	Oral	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1815454		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S				Teva
	Mycophenolate Mofetil			S				Teva
	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Procytox			S	Unknown	150 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173559	EXPEDITED (15-DAY)		OT	CA-ACCORD-196215		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness;	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled		Not Reported

Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Therapeutic Response Decreased	Enbrel	S	Subcutaneous	Syringe	Not Reported
	Hydroxychloroquine	S	Unknown	2 Every 1 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown	2 Every 1 Days	Not Reported
	Hydroxychloroquine	C	Unknown	2 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	1 Every 1 Weeks	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173561	EXPEDITED (15-DAY)		HO	CA-ACCORD-196009		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord
	Apo-Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Cefazolin			S				Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Pre-Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Frequency: 2 Every 1 Days		Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S				Not Reported
	Remicade			S		Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz	C	Oral	Frequency: 2 Every 1 Days		Not Reported
	Viread	C				Not Reported
	Naproxen	C		Frequency: 2 Every 1 Days		Not Reported
	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173562	EXPEDITED (15-DAY)		OT	CA-ACCORD-196058		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Unknown	Therapy Duration 365, Every 1 Days		Not Reported
	Leflunomide			S	Unknown	Every 1 Days		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous, 1 Every 1 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173565	EXPEDITED (15-DAY)		OT	CA-ACCORD-196089		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Therapeutic Product Effect Decreased; Toe	Methotrexate			S	Oral			Accord
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arnica Montana/Arnica Montana Extract/Arnica Montana Tincture			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Calcium			C				Not Reported
	Folic Acid			C				Not Reported

Amputation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173567	EXPEDITED (15-DAY)		OT	CA-ACCORD-195932			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Sulfasalazine			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173568	EXPEDITED (15-DAY)		OT	CA-ACCORD-195933			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Xeljanz			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Methotrexate			S	Subcutaneous			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173576	EXPEDITED (15-DAY)		OT	CA-ACCORD-196187			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

Enzyme Increased; Retinopathy	Sulfasalazine	S	2 Every 1 Days		Not Reported
	Hydroxychloroquine	S	2 Every 1 Days		Not Reported
	Xeljanz Xr	C	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173579	EXPEDITED (15-DAY)		OT	CA-ACCORD-196196		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S		1 Every 1 Days		Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173580	EXPEDITED (15-DAY)		OT	CA-ACCORD-196193		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate			S	Oral			Accord
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Remicade	S			Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173581	EXPEDITED (15-DAY)		OT	CA-ACCORD-196216		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Accord
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Intravenous (not otherwise specified)	Solution Subcutaneous, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173583	EXPEDITED (15-DAY)		DS	CA-ACCORD-196218		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173584	EXPEDITED (15-DAY)		OT	CA-ACCORD-196217		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling;	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Diclofenac	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular	Suspension Intraarticular	Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Xeljanz	C	Oral	2 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18173586	EXPEDITED (15-DAY)		OT	CA-ACCORD-196219		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174001	EXPEDITED (15-DAY)		OT	CA-ASTELLAS-2020US027593		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Prograf	S	Oral		Astellas
	Prograf	S	Oral		Astellas
	Prograf	S	Oral	Unk Unk, Unknown Freq.	Astellas
	Tacrolimus	S	Oral	4 Mg, Once Daily (2 Mg 2 Df Every 1 Day))	Astellas
	Tacrolimus	S	Oral	6 Mg, Once Daily (3 Mg 2 Df Every 1 Day)	Astellas
	Tacrolimus	S	Unknown	6 Mg, Once Daily (3 Mg 2 Df Every 1 Day)	Astellas
	Arava	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Cimzia	S	Subcutaneous	Unk Unk, Unknown Freq.	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk, Unknown Freq.	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unknown Freq.	Not Reported
	Hydroxychloroquine	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Neoral	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Rapamune	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Imuran [Azathioprine Sodium]	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174028	EXPEDITED (15-DAY)		OT	CA-ACCORD-196380		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Contraindicated Product Administered; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine]			S		1 Every 1 Days		Not Reported
	Rituximab/Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported
	Xeljanz			S		2 Every 1 Days		Not Reported
	Paracetamol			C				Not Reported
	Gabapentin			C		3 Every 1 Days		Not Reported
	Apo-Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174029	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04912		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On The First Day		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid-For The Following 4 Days		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Chloroquine			C	Unknown	500 Milligram, Bid		Not Reported
	Losartan			C	Intracardiac	50 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174038	EXPEDITED (15-DAY)		OT	CA-ACCORD-196376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174040	EXPEDITED (15-DAY)		OT	CA-ACCORD-196379		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174041	EXPEDITED (15-DAY)		OT	CA-ACCORD-196374		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Pre-Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Ergocalciferol			C				Not Reported
	Azathioprine			C				Not Reported
	Arthrotec			C				Not Reported
	Hydroxychloroquine			S		Frequency: 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174052	EXPEDITED (15-DAY)		OT	CA-ACCORD-196381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness;	Methotrexate			S		1 Every 1 Weeks		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported

Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single Use Prefilled Syringe	Not Reported
	Codeine	S			Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S			Not Reported
	Abatacept	S			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S			Not Reported
	Prednisone	C			Not Reported
	Tofacitinib	C			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174131	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA025377			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Product Use In	Infliximab Pfizer (Unknown)			S		Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, 2x/Day		Not Reported

Unapproved Indication; Synovitis	Etanercept	S		Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Minocycline	S		Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported

	Dilaudid	C	Unk	Not Reported
	Dilaudid	C	Unk	Not Reported
	Dilaudid	C	Unk	Not Reported
	Wellbutrin	C	Unk	Not Reported
	Wellbutrin	C	Unk	Not Reported
	Wellbutrin	C	Unk	Not Reported
	Bupropion Hydrochloride	C	Unk	Not Reported
	Hydromorphone Hydrochloride	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174231	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP007908		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Q.M.T.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Oral	3 Mg/Kg, Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Therapy Duration: 579 (Unit Unspecified)		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)	5 Mg, Q.O.D.		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)	5 Unk, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174276	EXPEDITED (15-DAY)		OT	NVSC2020BR161379		57 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Anosmia; Covid-19; Eating Disorder; Eye Pain; Headache; Hypoacusis; Influenza; Malaise; Ocular Discomfort; Product Use In Unapproved Indication; Vision Blurred; Visual Impairment; Vomiting	Xolair			S	Unknown	450 Mg, Q4w		Not Reported
	Xolair			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Novartis
	Azithromycin Dihydrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174520	EXPEDITED (15-DAY)		OT	CA-ACCORD-196028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Orencia			S	Subcutaneous	Not Specified		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
Sulfasalazine	C	Unknown	Not Specified		Not Reported
Wellbutrin	C	Unknown	Not Specified		Not Reported
Xeljanz	C	Unknown			Not Reported
Methotrexate	S	Unknown	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174528	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-195874			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174533	EXPEDITED (15-DAY)		HO	CA-ACCORD-196026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Intravenous (not otherwise specified)	Solution Subcutaneous,Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174534	EXPEDITED (15-DAY)		DS	CA-ACCORD-196024		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis;	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174537	EXPEDITED (15-DAY)		OT	CA-ACCORD-196027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174542	EXPEDITED (15-DAY)		OT	CA-ACCORD-196271		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174544	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-196063		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Injection Site Erythema; Injection Site Induration; Injection Site Inflammation; Injection Site Pruritus;	Methotrexate			S	Oral			Accord
	Quetiapine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Alendronic Acid			C				Not Reported
	Amlodipine			C				Not Reported
	Ativan			C	Unknown	Not Specified,As Required		Not Reported
	Lipitor			C		Not Specified		Not Reported
	Methadone			C	Oral	Not Specified		Not Reported
	Pantoloc			C				Not Reported
	Prednisone			C	Unknown	Not Specified		Not Reported
	Valtrex			C				Not Reported
	Zopiclone			C				Not Reported

Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174547	EXPEDITED (15-DAY)		OT	CA-ACCORD-196270		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174548	EXPEDITED (15-DAY)		OT	CA-ACCORD-196359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Intolerance; Rash; Rheumatoid Arthritis	Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Oral	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174562	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-257626		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Sun
	Azithromycin			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Pantroprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174780	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-257663		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Sun
	Azithromycin			S	Unknown	Unk		Sun
	Vancomycin Hydrochloride			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174940	EXPEDITED (15-DAY)		OT	CA-ACCORD-195934			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Methotrexate	S		1 Every 1 Weeks	Accord
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1 Every 6 Weeks	Not Reported
	Orencia	S			Not Reported
	Leflunomide	S		1 Every 1 Weeks	Not Reported
	Hydroxychloroquine	S	Oral	2 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous	1 Every 2 Weeks	Not Reported
	Enbrel	S		1 Every 2 Weeks	Not Reported
	Actemra	S			Not Reported
	Wellbutrin	C			Not Reported
	Sulfasalazine	C			Not Reported
	Xeljanz	C			Not Reported
	Methotrexate	S		1 Every 1 Weeks	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174941	DIRECT	N	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Rash; Urticaria	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174996	EXPEDITED (15-DAY)		OT	CA-ACCORD-196372			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174997	EXPEDITED (15-DAY)		DS, HO, LT	CA-ACCORD-196373		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Methotrexate			S		Frequency: 1 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Frequency: 1 Every 2 Days		Not Reported
	Anakinra			S	Subcutaneous	Frequency: 1 Every 1 Days		Not Reported
	Apo-Naproxen			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Enbrel			S	Subcutaneous	Frequency:1 Every 1 Weeks		Not Reported
	Etanercept			S	Subcutaneous	Frequency: 2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S		Route Of Administration: Inhalation, Frequency: 1 Every 1 Months		Not Reported
	Prednisone			S	Oral	Frequency: 2 Every 1 Days		Not Reported
	Sulfasalazine			S		Frequency: 1 Every 1 Days		Not Reported
	Triamcinolone			S	Intra-articular	Dosage Form: Suspension Intra-Articular		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks, Dosage: 15.0 Mg/M2		Not Reported

Actemra	S	Intravenous (not otherwise specified)	Frequency: 2 Every 1 Weeks	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)	Frequency: 1 Every 2 Weeks	Not Reported
Anakinra	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	Frequency:1 Every 1 Weeks	Not Reported
Enbrel	S	Subcutaneous	Frequency:1 Every 2 Weeks	Not Reported
Etanercept	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Not Reported
Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Frequency:1 Every 1 Days	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Frequency: 1 Every 6 Weeks	Not Reported
Infliximab	S		Frequency: 1 Every 1 Weeks	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Months	Not Reported
Orencia	S	Intravenous drip	Frequency: 1 Every 1 Months	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Months	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Months	Not Reported
Prednisone	S			Not Reported
Prednisone	S	Oral	Frequency: 2 Every 1	Not Reported

Days

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175006	EXPEDITED (15-DAY)		OT	CA-ACCORD-196461		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175008	EXPEDITED (15-DAY)		OT	DE-ACCORD-196072			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Hydroxychloroquine			S	Transplacental	300 Mg/D / Alternating: 200 And 400mg Daily		Not Reported
	Prednisolone			S	Transplacental	7.5 Mg/D		Not Reported
	Rhophylac			C	Transplacental			Not Reported
	Infliximab			C	Transplacental	Last Exposure Two Weeks Before Conception		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175015	EXPEDITED (15-DAY)		OT	CA-ACCORD-196375		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Methotrexate			S	Oral			Accord
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Endocervical			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Leflunomide	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Ciclosporin	S			Not Reported
	Leflunomide	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral	2 Every 1 Days	Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Accord
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175019	EXPEDITED (15-DAY)		OT	CA-ACCORD-196159			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175032	EXPEDITED (15-DAY)		OT	CA-ACCORD-195937		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175033	EXPEDITED (15-DAY)		OT	CA-ACCORD-195938		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure; Urticaria	Methotrexate	S			Not Reported
	Actemra	S			Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175038	EXPEDITED (15-DAY)		OT	CA-ACCORD-196265			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			C	Unknown	1 Every 1 Days		Not Reported
	Cosentyx			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175040	EXPEDITED (15-DAY)		OT	CA-ACCORD-196467		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175041	EXPEDITED (15-DAY)		OT	CA-ACCORD-196272		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C		Frequency: 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175561	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-258394		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Azithromycin		S	Unknown	Unk		Sun
	Hydroxychloroquine		S	Unknown	Unk		Ipca
	Vitamin C		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175563	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-258376		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Off Label Use	Azithromycin			S	Unknown	500 Milligram, Qd		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Enoxaparin Sodium			S	Unknown	6000 Ui Twice Daily		Not Reported
	Paracetamol			S	Unknown			Ohm Lab
	Ritonavir			S	Unknown	100 Milligram, Qd		Not Reported
	Darunavir			S	Unknown	800 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175564	EXPEDITED (15-DAY)		DE, HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-258392		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Vitamin C			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175721	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-067169		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Lyrica	S	Unknown			Not Reported
	Methotrexate	S	Oral	25 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral			Not Reported
	Remeron	S	Oral	15 Milligram		Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175834	EXPEDITED (15-DAY)		OT	NVSC2020DE225935			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Maternal Dose 7.5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose 300 [Mg/D]/ Alternating: 200 And 400mg Daily		Not Reported
	Infliximab			C	Transplacental	Last Exposure Two Weeks Before Conception		Not Reported
	Rhophylac			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18176023	EXPEDITED (15-DAY)		OT	CA-ACCORD-196164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-	Methotrexate			S	Subcutaneous			Accord
	Sulfasalazine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S				Not Reported

Responder	Actemra	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18176341	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1072209		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Tacrolimus			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid On The First Day		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid For The Following 4 Days		Mylan
	Chloroquine			S	Unknown	500 Milligram, Bid		Mylan
	Losartan			C	Unknown	50 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18176687	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200820196			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Ustekinumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Mercaptopurine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Pamidronate Disodium	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tenoxicam	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18177618	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1072599		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Chorioretinitis; Macular Degeneration; Necrotising Retinitis; Vitritis	Mycophenolate Mofetil			S	Unknown	1000 Milligram, Q8h		Mylan
	Prednisone			S	Unknown	5 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18177718	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1072538		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Covid-19; Impaired Self-Care; Mental Status Changes; Myasthenia Gravis Crisis; Off Label Use; Respiratory Failure	Azathioprine			S	Unknown			Mylan
	Azithromycin			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan
	Immunoglobulin /00025201/			S	Intravenous (not otherwise specified)			Mylan
	Immunoglobulin /00025201/			S	Intravenous (not otherwise specified)	He Received Immune-Globulin Daily For 5 Days		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18178415	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-067517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	12901853	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1.0 Gram		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Penicillamine			S	Unknown	Unk		Not Reported

Simponi	S	Subcutaneous	50 Milligram, Qmo		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	Unk		Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
Doxycycline	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Tobramycin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	13281112	EXPEDITED (15-DAY)		OT	CA-ROCHE-1898409		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Abatacept			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

Tramadol	C	Unknown	Not Reported
Indocine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	14119590	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP020045		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cefazolin			S	Unknown			Apotex
	Apo-Leflunomide			S	Oral	10 Milligram		Apotex
	Leflunomide			S	Oral	10 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Apotex
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Viread			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Naproxen			C	Unknown	500 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	14128229	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020204		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Apotex
	Leflunomide	S	Oral	20 Mg, Qd	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil /00072602/	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Milligram, Qd	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Q.Wk.	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	C	Unknown	17 Milligram	Not Reported
	Methotrexate	C	Unknown	15 Mg, Q.Wk.	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Q.Wk.	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Q.Wk.	Not Reported

Methotrexate	C	Unknown	17.5 Milligram		Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qd		Not Reported
Sulfasalazine	C	Oral	1 G, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Depo-Medrol	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk		Not Reported
Methylprednisolone Acetate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	14931475	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP013687		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Minocycline			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Myochrysine			S	Parenteral	Unk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Otezla			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported

Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Sirukumab	S	Unknown	Unk		Not Reported
Adalimumab	S	Subcutaneous	Unk		Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported
Etanercept	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Oral	5 Mg, Bid		Not Reported
Stelara	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Salazopyrin	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	250 Milligram		Not Reported
Minocin	S	Unknown	Unk		Not Reported
Apremilast	S	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Abatacept	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Orencia	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	16767573	EXPEDITED (15-DAY)		OT	PHHY2018CA068442		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown			Novartis

Adalimumab	S	Subcutaneous	40 Mg, Biw	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Mg	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Biw	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Apo Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Oral	Unk	Not Reported
Apo Leflunomida	S	Unknown		Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Unknown	75 Mg, Qw	Not Reported

	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	40 Mg, Biw	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Subcutaneous	Unk	Not Reported
	Risedronate	C	Oral	35 Mg, Qw	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	17641316	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Desoximetasone	S	Unknown		Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Quetiapine	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	17743721	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034889		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra	S	Subcutaneous		Not Reported
	Actonel	S	Unknown	35 Milligram, Qwk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Plaquenil S	S	Unknown	300 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	17847019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606601		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S		Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported

Mellitus; Wound	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Subcutaneous		Not Reported
	Rituxan	S			Not Reported
	Salazopyrine	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	Gastro-Resistant Tablet	Not Reported
	Sulfasalazine	S	Oral	Gastro-Resistant Tablet	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Topicort Lp	S	Subcutaneous		Not Reported
	Winpred	S	Oral		Not Reported
	Ustekinumab	S	Intravenous (not		Not Reported

			otherwise specified)	
	Otezla	S	Oral	Not Reported
	Reactine (Canada)	S	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	17852850	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005005786			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	17889904	EXPEDITED (15-DAY)		OT	DE-ACCORD-185184		62 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Laser Surgery; Retinal Tear	Hydroxychloroquine			S	Oral			Not Reported
	L-Thyroxine Henning			C	Oral	75 Ug,Long-Term Medication		Not Reported
	Lamotrigine			C	Oral	50 Mg,Long-Term Medication		Not Reported
	Brintellix			C	Oral	Long-Term Medication,10mg		Not Reported
	Paracetamol			C				Not Reported
	Levothyroxine			C	Oral	75 Microg,1-0-0 Long-Term Medication		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18100506	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP014688		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Apo-Leflunomide		S	Oral	10 Milligram	Apotex
	Hydroxychloroquine		S	Unknown	200 Milligram, Bid	Apotex
	Cefazolin		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Methotrexate		S	Subcutaneous	25 Milligram, Q.Wk.	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Viread		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	500 Milligram, Bid	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18101399	EXPEDITED (15-DAY)		OT	CA-ACCORD-193655			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased	Methotrexate			S	Unknown			Accord
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18119847	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1810160		69 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatotoxicity; Transaminases Increased	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported
	Plaquinol			S	Oral	400 Mill Equivalents,400mg 12 / 12h In D0 And Then 200mg 12 / 12h		Not Reported
	Metoclopramide			C	Oral	10 Mg		Not Reported
	Allopurinol			C	Oral	100 Mg,24/24h		Not Reported
	Cetirizine			C	Oral	10 Mg		Not Reported
	Amoxicillin, Clavulanic Acid			C	Oral	2 Dosage Forms,8/8h		Not Reported
	Piperacillin, Tazobactam			C		1 Cp 8h/8h,2 Dosage Forms		Not Reported
	Metamizole Magnesium			C	Oral	575 Mg,Sos		Not Reported
	Alfuzosin			C	Oral	10 Milligram Daily; 1 Cp 1xday		Not Reported
	Paracetamol			C	Oral	1000mg Sos		Not Reported
	Atenolol			C	Oral	50 Mg ,1 Cp 24/24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18122323	EXPEDITED (15-DAY)		OT	CA-ACCORD-194316		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous drip	1 Every 6 Months		Not Reported
	Prednisone			S				Not Reported
	Orencia			S				Not Reported

Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Hydroxychloroquine	S				Not Reported
	Humira	S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Arava	S				Not Reported
	Prednisone	S				Not Reported
	Actemra	S				Not Reported
	Risedronic Acid	C				Not Reported
	Sulfasalazine	S		2 Every 1 Days		Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Accord
	Prednisone	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18151293	EXPEDITED (15-DAY)		OT	CA-ACCORD-195344		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate			S		1 Every 1 Weeks		Accord
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	1 Every 1 Months		Not Reported
	Xeljanz			S				Not Reported
	Adalimumab			C				Not Reported
	Prednisone			C		1 Every 1 Days		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18177216	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-039322		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis Crisis	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	200 Milligram, 3 Times A Day		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported
	Immunoglobulin			C	Intravenous (not otherwise specified)	Unk, 1 Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18177546	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202008008043			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonitis; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18177547	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202008007835			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported
	Meropenem			S		Unk		Not Reported
	Furosemide			S		Unk		Not Reported
	Piperacillin-Tazobactam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18177745	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04883		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Meropenem			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Piperacillin & Tazobactam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18178189	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-04			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic;	Mobicox			S	Unknown			Boehringer Ingelheim
	Meloxicam			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Intramuscular			Not Reported

Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18178445	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-040192		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Oral	Unspecified		Aurobindo
	Linezolid			S	Intravenous drip	Unspecified		Aurobindo
	Tienam			S	Intravenous drip	Unspecified		Not Reported
	Plaquenil			S	Oral	Unspecified		Not Reported
	Tazocilline			S	Intravenous drip	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18178569	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1817942		33 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Covid-19; Diarrhoea; Febrile Neutropenia; Off Label Use; Pancytopenia	Paclitaxel			S	Unknown	Along With Ifosfamide; Multi-Cycle Hdct Ti-Ce Regimen		Not Reported
	Paclitaxel			S				Not Reported
	Paclitaxel			S				Not Reported
	Carboplatin			S	Unknown	Area Under The Concentration-Time Curve (Auc) 7 Along With Etoposide For Three Days; Third Cycle ...		Not Reported
	Carboplatin			S				Not Reported
	Carboplatin			S				Not Reported
	Etoposide			S	Unknown	400 Mg/Sqm Along With Carboplatin For Three Days; Third Cycle Of Hdct Regimen Initiated On 14th		Teva

				M...	
	Etoposide	S			Teva
	Etoposide	S			Teva
	Ifosfamide	S	Unknown	Along With Paclitaxel; Multi-Cycle Hdct Ti-Ce Regimen	Not Reported
	Ifosfamide	S			Not Reported
	Ifosfamide	S			Not Reported
	Ritonavir	S	Oral	100 Milligram Daily;	Not Reported
	Darunavir	S	Oral	800 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Levofloxacin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18178710	EXPEDITED (15-DAY)		HO, OT	MA-LUPIN PHARMACEUTICALS INC.-2020-04885		76 YR	Female	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Septic Shock	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18178767	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Amoxicillin Trihydrate/Clavulanate Potassium	C	Unknown			Not Reported
Amoxil [Amoxicillin]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18178974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-065736			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179144	EXPEDITED (15-DAY)		HO, OT	BE-LUPIN PHARMACEUTICALS INC.-2020-04786		50 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Reaction With Eosinophilia And Systemic Symptoms; Off Label Use	Azithromycin	S	Unknown	Unk		Lupin
	Hydroxychloroquine	S	Unknown	Unk		Lupin
	Heparine [Heparin]	C	Unknown	Unk		Not Reported
	Propofol	C	Unknown	Unk		Not Reported
	Clonidine	C	Unknown	Unk		Not Reported
	Norepinephrine	C	Unknown	Unk		Not Reported
	Sufentanil	C	Unknown	Unk		Not Reported
	Rocuronium	C	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk (9 Days Before Admission)		Not Reported
	Sevoflurane	C	Unknown	Unk (8 Days Before Admission)		Not Reported
	Cefuroxime	C	Unknown	Unk (6 Days Before Admission)		Not Reported
	Flucloxacilline [Flucloxacillin]	C	Unknown	Unk (4 Days Before Admission)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179158	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05019		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Enoxaparin			C	Subcutaneous	40 Milligram, Qd		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Milligram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179204	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS		60 YR	Female	USA

INC.-2020-05020

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Lupin
	Enoxaparin			C	Subcutaneous	40 Milligram, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Milligram, Bid		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179289	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016363		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Hot Flush; Nausea; Rhinorrhoea; Sinus Congestion	Leflunomide			S	Unknown	10 Milligram, Qd		Apotex
	Methotrexate			S	Oral	25 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179392	EXPEDITED (15-DAY)		OT	CA-ACCORD-196470		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Leflunomide			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported

Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine	S				Not Reported
	Leflunomide	S				Not Reported
	Orencia	S				Not Reported
	Rituximab	S	Intravenous drip			Not Reported
	Sulfasalazine	S				Not Reported
	Xeljanz	C	Oral	Frequency: 2 Every 1 Days		Not Reported
	Pantoprazole	C		Frequency: 3 Every 1 Days		Not Reported
	Loperamide	C	Oral			Not Reported
	Align	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179393	EXPEDITED (15-DAY)		OT	CA-ACCORD-196472			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported

	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179396	EXPEDITED (15-DAY)		OT	CA-ACCORD-196491			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Neutropenia	Methotrexate			S	Unknown			Accord
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Kevzara			C	Unknown			Not Reported
	Azathioprine			C	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179406	EXPEDITED (15-DAY)		OT	CA-ACCORD-196455		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Etanercept			S				Not Reported
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Tocilizumab			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179407	EXPEDITED (15-DAY)		OT	CA-ACCORD-196441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate		S			Accord
	Actemra		S	Subcutaneous		Not Reported
	Apo-Leflunomide		S			Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S			Not Reported
	Orencia		S			Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179408	EXPEDITED (15-DAY)		HO	CA-ACCORD-196442			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Accord
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Frequency: 1 Every 2 Weeks, Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179497	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1816031		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis; Renal Colic	Hidroxicloroquina (2143a)	S	Oral	400 Mg / 12h 1 Day Followed By 400 Mg Day, Unit Dose: 400mg		Teva
	Hidroxicloroquina (2143a)	S	Oral	400mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179693	EXPEDITED (15-DAY)		OT	CA-ACCORD-196446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate			S	Unknown	Not Specified		Accord
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Gabapentin			C	Unknown	Not Specified		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179694	EXPEDITED (15-DAY)		OT	CA-ACCORD-196443			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Intolerance; Eye Disorder; Lung Disorder; Macular Degeneration	Methotrexate			S				Accord
	Arava			S				Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179705	EXPEDITED (15-DAY)		OT	ALC2020CA006622			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Erelzi [Etanercept]			S	Unknown			Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown	Not Reported
Calcium Gluconate	C	Unknown	Not Reported
Quetiapine	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179716	EXPEDITED (15-DAY)		OT	CA-ACCORD-196478		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179718	EXPEDITED (15-DAY)		CA, HO	CA-ACCORD-196485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral	1 Every 24 Hours		Not Reported

Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Celebrex	S	Oral	1 Every 24 Hours	Not Reported
	Hydroxychloroquine	S			Not Reported
	Myochrysine	S	Intramuscular	1 Every 1 Weeks	Not Reported
	Remicade	S			Not Reported
	Sulfasalazine	S			Not Reported
	Isoniazid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179870	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04832		26 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticaria	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Loading Dose)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram Weekly		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179871	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04830		37 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticaria	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Loading Dose)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram Weekly		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179874	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04913		38 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Oseltamivir			S	Oral	Unk		Lupin
	Ceftriaxone			S	Unknown	Tapered Off After Starting Of Vancomycin And Meropenem		Lupin
	Azithromycin			S	Unknown	Tapered Off After Starting Of Vancomycin And Meropenem		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Cisatracurium			S	Unknown	Administered With Propofol Infusion		Not Reported
	Fresh Frozen Plasma			S	Unknown	2 Units Were Transfused		Not Reported
	Fentanyl			S	Unknown	Administered With Propofol Injection		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Propofol			S	Unknown	Administered With Fentanyl		Not Reported
	Propofol			S	Unknown	Administered With Cisatracurium Besilate		Not Reported
	Norepinephrine			S	Unknown	Moderate Dose		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18179920	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05021		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Lupin
	Enoxaparin			C	Subcutaneous	40 Milligram, Qd		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180095	EXPEDITED (15-DAY)		OT	QA-LUPIN PHARMACEUTICALS INC.-2020-04942		26 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Oseltamivir			S	Oral	150 Milligram Unk		Lupin
	Ceftriaxone			S	Unknown	2 Gram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			C	Oral	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180238	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202008008023			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Hepatic Cirrhosis; Musculoskeletal Stiffness; Off Label Use; Product Use Issue	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Lipitor	C		Unk	Not Reported
	Celebrex	C		Unk	Not Reported
	Mirtazapine	C			Not Reported
	Calcium	C			Not Reported
	Vitamin D [Colecalciferol]	C			Not Reported
	Pantoloc	C			Not Reported
	Citalopram	C			Not Reported
	Plavix	C			Not Reported
	Bisoprolol	C			Not Reported
	Prednisone	C		Unk	Not Reported
	Tylenol	C			Not Reported
	Rivotril	C			Not Reported
	Cbd Oil	C			Not Reported
	Cimzia	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180313	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP016167		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, One Every Four Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180325	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180501	EXPEDITED (15-DAY)		OT	CA-ACCORD-196456		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Accord
	Adalimumab			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
Sarilumab	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S				Not Reported
Tocilizumab	S				Not Reported
Xeljanz	S	Oral	2 Every 1 Days		Not Reported
Folic Acid	C				Not Reported
Rabeprazole	C	Oral	1 Every 1 Days		Not Reported
Methotrexate	S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180502	EXPEDITED (15-DAY)		OT	CA-ACCORD-196513		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 24 Hours		Not Reported
	Infliximab			S	Unknown	1 Every 24 Hours, Not Specified		Not Reported
	Prednisone			S	Unknown	1 Every 24 Hours		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Arava			S	Oral	1 Every 24 Hours		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180871	EXPEDITED (15-DAY)		OT	GB-ACCORD-196555		47 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Disorientation; Headache; Herbal Interaction; Hyperhidrosis; Musculoskeletal Pain; Seizure; Somnolence	Hydroxychloroquine			S				Not Reported
	Celestial Sleepytime			S	Oral	Tea Sachet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180875	EXPEDITED (15-DAY)		OT	CA-ACCORD-196538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Vomiting	Methotrexate			S	Subcutaneous			Accord
	Baricitinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180999	EXPEDITED (15-DAY)		OT	CA-ACCORD-196527			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)			
	Leflunomide	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	C				Not Reported
	Desoximetasone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181176	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816417			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181478	EXPEDITED (15-DAY)		OT	CA-ACCORD-196436		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Drug Intolerance; Therapeutic Product Effect Decreased	Methotrexate	S	Oral		Accord
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181479	EXPEDITED (15-DAY)		OT	CA-ACCORD-196248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown	1 Every 1 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181482	EXPEDITED (15-DAY)		OT	CA-ACCORD-196293			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Methotrexate			S	Oral			Accord
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181493	EXPEDITED (15-DAY)		OT	CA-ACCORD-196435		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Spinal Column Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mobicox			C	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181494	EXPEDITED (15-DAY)		OT	CA-ACCORD-196437		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Methotrexate	S	Subcutaneous	Accord
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181495	EXPEDITED (15-DAY)		OT	CA-ACCORD-196512		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Paracetamol			C				Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cymbalta			C				Not Reported
	Elavil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex			C				Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C				Not Reported

	Sumatriptan	C	Not Reported
	Tenormin	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181497	EXPEDITED (15-DAY)		HO	CA-ACCORD-196247		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Methotrexate			S	Unknown			Accord
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18181560	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020319723		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Ceftriaxone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported

Losartan	C		Unk		Not Reported
Insulin	C		Unk		Not Reported
Metformin	C		Unk		Not Reported
Glipizide	C		Unk		Not Reported
Citalopram	C		Unk		Not Reported
Folate	C		Unk		Not Reported
Cholecalciferol	C		Unk		Not Reported
Fluticasone	C	Nasal	Unk		Not Reported
Betamethasone	C	Topical	Unk		Not Reported
Fluocinonide	C		Unk		Not Reported
Lisinopril	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18182308	EXPEDITED (15-DAY)		OT	NVSC2020BE231136		50 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported
	Propofol			S	Unknown	Unk		Not Reported
	Clonidine			S	Unknown	Unk		Not Reported
	Norepinephrine			S	Unknown	Unk		Not Reported
	Sufentanil			S	Unknown			Not Reported
	Rocuronium			S	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 Mg/Kg, Qd		Not Reported
	Methylprednisolone			C	Unknown	80 Mg, Qd		Not Reported
	Methylprednisolone			C	Unknown	40 Mg, Qd		Not Reported
	Methylprednisolone			C	Unknown	20 Mg, Qd		Not Reported
	Methylprednisolone			C	Unknown	8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18182321	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1072695		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S		200 Milligram Received One Dose		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18182549	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-066252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Edta [Edetate Disodium]			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira Ac			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Phenylephrine Hydrochloride			S	Intramuscular			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported

Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sodium Perborate	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Unknown	10 Milligram, Q2wk	Not Reported
Xeljanz	S	Unknown	5 Milligram	Not Reported
Xeljanz	S	Subcutaneous	5 Milligram	Not Reported
Celebrex	C	Unknown		Not Reported
Ibuprofen	C	Unknown		Not Reported
Lipitor [Atorvastatin]	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18182554	EXPEDITED (15-DAY)		HO	CN-JNJFOC-20200826682			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Cerebral Haemorrhage; Drug-Induced Liver Injury; Electrolyte Imbalance; Gastrointestinal Haemorrhage; Gastrointestinal Infection; Hyperglycaemia; Hyperkalaemia; Hypernatraemia; Hypertension; Hypocalcaemia; Hypokalaemia; Hyponatraemia; Infection; Lower Respiratory Tract Infection; Oral Infection; Pneumonia; Respiratory	Ibuprofen			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Penicillin /00000901/			S	Unknown			Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Aztreonam			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Moxifloxacin			S	Unknown			Not Reported
	Methazolamide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Roxithromycin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

Failure; Rhabdomyolysis; Skin Infection; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; Transaminases Increased; Urinary Tract Infection; Viral Infection	Metronidazole	S	Unknown	Not Reported
	Tinidazole	S	Unknown	Not Reported
	Gentamicin	S	Unknown	Not Reported
	Amikacin	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Carbamazepine	S	Unknown	Not Reported
	Sodium Valproate	S	Unknown	Not Reported
	Phenytoin Sodium	S	Unknown	Not Reported
	Lamotrigine	S	Unknown	Not Reported
	Benzbromarone	S	Unknown	Not Reported
	Oxcarbazepine	S	Unknown	Not Reported
	Metamizole Sodium	S	Unknown	Not Reported
	Aspirin /00002701/	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Nimesulide	S	Unknown	Not Reported
	Cisplatin	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Thalidomide	S	Unknown	Not Reported
	Fexofenadine	S	Unknown	Not Reported
	Gabapentin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2020	14751341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009613		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex

Hydroxychloroquine	S	Unknown	20 Unk		Apotex
Actemra	S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
Orencia	S	Unknown	750 Mg, Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18043036	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-191170			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone/Prednisone Acetate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18122911	EXPEDITED (15-DAY)		OT	AU-ACCORD-194007			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Impaired Quality Of Life; Impaired Work Ability; Off Label Use; Treatment Failure	Hydroxychloroquine			S		Daily		Not Reported
	Montelukast			S				Not Reported
	Plaquenil			S				Not Reported
	Fexofenadine/Fexofenadine Hydrochloride			S		Three Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184065	EXPEDITED (15-DAY)		OT	CA-ACCORD-196269		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Prednisone			C				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184071	EXPEDITED (15-DAY)		OT	CA-ACCORD-196267		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Methotrexate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Lasix	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Iron	C	Unknown	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Paracetamol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184072	EXPEDITED (15-DAY)		OT	CA-ACCORD-196268		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased;	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Sodium Aurothiomalate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Cephalexin	C	Unknown	4 Every 1 Days	Not Reported
	Perindopril	C	Unknown		Not Reported
	Prednisone	C	Unknown	1 Every 1 Days	Not Reported
	Hydroxychloroquine	C			Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184073	EXPEDITED (15-DAY)		OT	CA-ACCORD-196284			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S		1 Every 1 Weeks		Accord
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 6 Weeks		Not Reported
	Orencia			S				Not Reported
	Leflunomide			S		1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S		2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Actemra			S				Not Reported
	Enbrel			S		1 Every 2 Weeks		Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

	Methotrexate	S	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184074	EXPEDITED (15-DAY)		OT	CA-ACCORD-196274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous, Frequency: 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S		Frequency: 1 Every 1 Weeks		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			C				Not Reported
	Gabapentin			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184079	EXPEDITED (15-DAY)		OT	CA-ACCORD-196351			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		1 Every 1 Weeks		Not Reported

Extremity; Pain In Jaw; Rheumatoid Arthritis	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S		Not Reported
	Tofacitinib		S		Not Reported
	Paracetamol		C		Not Reported
	Gabapentin		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184081	EXPEDITED (15-DAY)		OT	CA-ACCORD-196378			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C		1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18184084	EXPEDITED (15-DAY)		OT	CA-ACCORD-196385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Methotrexate			S				Not Reported
	Arava			S		1 Every 1 Days		Not Reported
	Codeine			S				Not Reported
	Ibuprofen			S				Not Reported
	Plaquenil			S				Not Reported

	Rosuvastatin	S	1 Every 1 Days		Not Reported
	Tylenol	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18272960	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Treatment Noncompliance	Azithromycin			S			5 DAY	Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18273083	DIRECT					40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Use Issue; Treatment Noncompliance	Azithromycin			S			5 DAY	Not Reported
	Hydroxychloroquine			S			5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	11257960	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-046061		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Leflunomide	S	Unknown	Unk	Not Reported
Gold	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	1 Ml, Qwk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	7 Mg, Qd	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Mycophenolic Acid	S	Unknown		Not Reported
Methotrexate	S	Unknown	1 Milliliter	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	1 Gram; 2 Every 1 Day	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	C	Oral	5.0 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	12367074	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-034237		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Orencia	S	Intravenous (not otherwise specified)	780 Milligram, Qwk	Bristol Myers Squibb
	Orencia	S	Unknown	760 Milligram, Qwk	Bristol Myers Squibb
	Orencia	S	Intravenous (not otherwise specified)	780 Milligram, Qwk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	360 Milligram, Qmo	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	680 Milligram, Q4wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	2.68 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
	Alendronate Sodium	S	Oral	70 Milligram, Qwk	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Codeine Sulphate	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	380 Milligram	Not Reported

Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported

Prednisone	C	Unknown	20 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Simponi	S	Unknown	680 Milligram, Qmo	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Unknown	1000 Milligram, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Etanercept	S	Unknown	25.0 Milligram, Qwk	Not Reported
Etanercept	S	Unknown	50 Milligram, Qwk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Qcycle	Not Reported
Celebrex	S	Unknown		Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Prednisolone	C	Unknown	10 Milligram, Qd	Not Reported
Ciclosporin	C	Unknown	150 Milligram 1 Every 24	Not Reported

	Ciclosporin		C	Unknown	Days 150 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	12766798	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076609		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram, Qwk		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram, Qwk		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram (11 Every 1 Week)		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Naprosyn [Naproxen]			C	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	12913291	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS		60 YR	Female	CAN

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BMS-2016-092198

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Oral	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Kineret			S	Subcutaneous	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	100 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qwk		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Cortisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	14750177	EXPEDITED (15-DAY)		OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-031026		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Influenza Vaccine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	15374470	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown	Unk		Apotex
	Acetaminophen			S	Endocervical	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Prednisone			S	Oral	20 Nanogram		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	25 Mg, Q.Wk.	Not Reported
	Methotrexate	C	Unknown	20 Milligram, Q.Wk.	Not Reported
	Methotrexate	C	Unknown	Unk, 1 Every 4 Weeks	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	16079910	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05962		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea;	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution, Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Other	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported

	Apo-Prednisone	S	Oral			Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension, Unknown		Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Triamcinolone	C	Other	Unknown		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	16079932	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	16577336	EXPEDITED (15-DAY)		HO, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-213482		75 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Eye Haematoma; Haematoma; Herpes Zoster; Lymphoma; Pulmonary Tuberculosis; Pyrexia; Treatment Failure; Tuberculosis; Uveitis	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Amphotericin B			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	17477823	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06466			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown (Solution)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Synovitis; Underdose; Vomiting	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Unknown	Unknown	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone Acetonide		S	Unknown	Unknown, Suspension Intraarticular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	17726004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	17875160	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2020US019202		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Tacrolimus			S	Oral	Unk, Unknown Freq.		Astellas
	Azathioprine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	17889330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2619913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	17915649	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-048453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cetrizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Enbrel	S	Unknown			Not Reported
Arava	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Etanercept	S	Unknown	Unk		Not Reported
Erelzi [Etanercept]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	17920409	EXPEDITED (15-DAY)		HO	NVSC2020FR172308		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Paracetamol			S	Oral	4 G, Qd		Novartis
	Augmentin			S	Intravenous (not otherwise specified)	3 G, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Amlor			S	Oral	1 Df, Qd		Not Reported
	Arimidex			S	Oral	1 Mg, Qd		Not Reported
	Nefopam			S	Oral	80 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	17975301	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1795750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr

	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18057415	EXPEDITED (15-DAY)		DE, OT	NVSC2020BR206554			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death Neonatal; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Novartis
	Azithromycin			S	Transplacental	Unk		Not Reported
	Fentanyl			S	Transplacental	Unk		Not Reported
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Oseltamivir			S	Transplacental	Unk		Not Reported
	Midazolam			S	Transplacental	Unk		Not Reported
	Norepinephrine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18058165	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-036047		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Syncope	Azithromycin			S	Oral	500 Milligram, 1 Total, Single		Aurobindo
	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Sotalol			S	Unknown	Unk,Interrupted 24 Hours		Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Before Hcq/Azt Initiation 200 Milligram, 3 Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18064962	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-03516		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Long Qt Syndrome; Myalgia; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Rosuvastatin			S	Unknown	Unk		Lupin
	Atorvastatin Calcium			S	Unknown	Unk		Lupin
	Oseltamivir			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Insulin Lispro			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Apixaban			C	Unknown	Unk		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)			Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Doxycycline			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Cisatracurium			C	Intravenous (not otherwise specified)			Not Reported

	Heparin		C	Intravenous (not otherwise specified)	Unk	Not Reported
	Atenolol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18065284	EXPEDITED (15-DAY)		OT	CA-ACCORD-191984		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Intravenous (not otherwise specified)	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Not Specified		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18066780	NON-EXPEDITED			US-PFIZER INC-2020282064		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18068077	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-191916		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective;	Methotrexate			S	Unknown	1 Every 1 Months, Not		Accord

Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra	S	Intravenous (not otherwise specified)	Solution For Injection Not Specified	Not Reported
	Arava	S	Oral	1 Every 1 Days	Not Reported
	Cimzia	S	Unknown	Single-Use Prefilled Syringe, Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	1 Every 2 Weeks,Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
	Arava	S	Oral	1 Every 1 Days	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Solution For Infusion	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18125451	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200804009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter	Simponi			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Infection; Hypersensitivity; Infusion Related Reaction; Pericarditis; Swelling; Wound	Cortisone Acetate		S	Unknown	Not Reported
	Desoximetasone		S	Oral	Not Reported
	Desoximetasone		S	Cutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Plaquenil /00072602/		S	Oral	Not Reported
	Pseudoephedrine Hydrochloride W/Tri/00005601/		S	Unknown	Not Reported
	Reactine /00884302/		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Fosamax		S		Not Reported
	Phenylephrine Hydrochloride		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18140188	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-25238		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18156598	EXPEDITED (15-DAY)		HO, OT	TR-ACCORD-196341		65 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184077	EXPEDITED (15-DAY)		OT	CA-ACCORD-196290			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported

Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Sulfasalazine		S	Unknown	Not Specified	Not Reported
	Leflunomide		S	Unknown		Not Reported
	Etanercept		C	Unknown		Not Reported
	Humira		C	Unknown	Solution Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184228	EXPEDITED (15-DAY)		HO, LT	CA-CELLTRION INC.-2020CA025570			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	500.0 Mg			Not Reported
	Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184301	EXPEDITED (15-DAY)		HO, LT, OT	CA-CELLTRION INC.-2020CA025631			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S		Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S				Not Reported

Methotrexate	S	Intra-arterial		Not Reported
Methotrexate	S			Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S			Not Reported
Oxycodone	S	Unknown	10 Mg	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sodium Aurothiomalate	S			Not Reported
Sodium Aurothiomalate	S			Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	1 Df, 1 Every 12 Hours	Not Reported
Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184344	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-04915		43 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Vomiting	Oseltamivir			S	Unknown	75 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Unk		Lupin
	Ribavirin			S	Unknown	2.4 Gram, Qd		Not Reported
	Prednisolone			C	Unknown	50 Milligram, Unk		Not Reported
	Prednisolone			C	Unknown	30 Milligram, Unk		Not Reported
	Prednisolone			C	Unknown	15 Milligram, Unk		Not Reported

Mycophenolate Mofetil	C	Unknown	2 Gram, Qd	Not Reported
Lopinavir/Ritonavir	C	Unknown	1 Dosage Form, Unk	Not Reported
Rituximab	C	Unknown	500 Mg Unk For 4 Weeks	Not Reported
Bisoprolol	C	Unknown	Unk	Not Reported
Tamsulosin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Levofloxacin	C	Unknown	750 Milligram Unk	Not Reported
Triamterene Hctz	C	Unknown	Unk	Not Reported
Vancomycin	C	Unknown	Unk	Not Reported
Finasteride	C	Unknown	Unk	Not Reported
Meropenem	C	Intravenous (not otherwise specified)	Unk	Not Reported
Losartan	C	Unknown	Unk	Not Reported
Immunoglobulins Nos	C	Intravenous (not otherwise specified)	Unk (High-Dose)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184464	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816381		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184467	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816553		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184469	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816425		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184471	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1816605		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Cefazolin			S	Intramuscular			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Arava	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Viread	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184474	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816330		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184475	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816361		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr

Arthritis	Minocycline		S	Unknown	Actavis
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184484	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816533		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Azathioprine	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Ivax
	Leflunomide	S	Unknown	Barr
	Medroxyprogesterone Acetate	S	Unknown	Barr
	Methotrexate	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Actavis
	Prednisone	S	Unknown	Actavis
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Anakinra	C		Not Reported
	Cyclosporine	C	Unknown	Not Reported
	Depo-Provera	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Rate Abnormal; Synovitis	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Parenteral	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184489	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816478		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Leflunomide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184496	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dactylitis; Drug Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184500	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816315			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184505	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1816459		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184574	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1817193		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Indometacin			S	Unknown			Actavis
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	25 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Cymbalta	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184581	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1817254		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Indometacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Prednisone			S	Oral	25 Mg		Actavis
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184661	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-258031		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis Crisis; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184770	EXPEDITED (15-DAY)		HO, OT	QA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-257821		26 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Glucose-6-Phosphate Dehydrogenase Deficiency; Off Label Use	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Daily		Sun
	Ceftriaxone			S	Unknown	2 Gram, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Ipca
	Lopinavir/Ritonavir			S	Oral	400 Mg/100 Mg, Bid		Not Reported
	Oseltamivir			S	Oral	150 Milligram, Bid		Not Reported
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184837	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04881		74 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Lupin
	Enoxaparin	C	Unknown	6000 Unit	Not Reported
	Lopinavir/Ritonavir	C	Unknown	2 Dosage Form, Bid (Lopinavir 200 Mg/Ritonavir 50 Mg Two Tablets Two Times Per Day)	Not Reported
	Dexamethasone	C	Unknown	20 Milligram	Not Reported
	Tocilizumab	C	Subcutaneous	162 Milligram (2 Cycles A Week Injection)	Not Reported
	Tocilizumab	C		5 Milligram, Bid (5 Mg Was Administered 2 Tablets Per Day For 2 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18184852	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04895		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Unk		Lupin
	Enoxaparin			C	Unknown	6000 Unit		Not Reported
	Lopinavir/Ritonavir			C	Unknown	2 Dosage Form, Bid (Lopinavir 200 Mg/Ritonavir 50 Mg Two Tablets Two Times Per Day)		Not Reported
	Ruxolitinib			C	Unknown	5 Milligram, Bid (5 Mg Was Administered 2 Tablets Per Day For 3 Days)		Not Reported
	Ruxolitinib			C	Unknown	10 Milligram, Bid		Not Reported
	Ruxolitinib			C	Unknown	5 Milligram, Qd		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18185222	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05011			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Hypokinesia	Ceftriaxone			S	Transplacental	500 Milligram, Unk		Lupin
	Azithromycin			S	Transplacental	250 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Transplacental	400 Milligram, Bid (For Two Doses)		Lupin
	Hydroxychloroquine			S	Transplacental	200 Milligram, Bid (For Eight Doses)		Lupin
	Methylprednisolone			S	Transplacental	125 Milligram, (One Dose)		Lupin
	Methylprednisolone			S	Transplacental	40 Milligram, Bid		Lupin
	Methylprednisolone			S	Transplacental	20 Milligram, Qd (Tapered Over 5 Days0		Lupin
	Betamethasone			S	Transplacental	12 Milligram, Qd (Single Dose Repeated For One Dose 24 Hours Later)		Lupin
	Remdesivir			S	Transplacental	200 Milligram, Qid		Not Reported
	Remdesivir			S	Transplacental	100 Milligram, Qd (Nine Doses)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18185223	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04872		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	500 Milligram, Unk (Course Completed)		Lupin
	Azithromycin			S	Oral	250 Milligram, Qd (Course Completed)		Lupin
	Hydroxychloroquine			S	Oral	400 Milligram, Bid (For Two Doses)		Lupin

	Hydroxychloroquine	S	Oral	200 Milligram, Bid (For Eight Doses) (Course Completed)	Lupin
	Methylprednisolone	S	Intravenous (not otherwise specified)	125 Milligram, (One Dose)	Lupin
	Methylprednisolone	S	Intravenous (not otherwise specified)	40 Milligram, Bid	Lupin
	Methylprednisolone	S	Intravenous (not otherwise specified)	20 Milligram, Qd (Tapered Over 5 Days0	Lupin
	Betamethasone	S	Intramuscular	12 Milligram, Qd (Single Dose Repeated For One Dose 24 Hours Later)	Lupin
	Remdesivir	S	Intravenous (not otherwise specified)	200 Milligram, Qid	Not Reported
	Remdesivir	S	Intravenous (not otherwise specified)	100 Milligram, Qd (Nine Doses) (Course Completed)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186497	EXPEDITED (15-DAY)		OT	CA-ACCORD-196509		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Arthrotec	C	Unknown			Not Reported
	Azathioprine	C				Not Reported
	Ergocalciferol	C		Not Specified		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187037	EXPEDITED (15-DAY)		OT	NVSC2020US231607		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate Tablets Usp			S	Other	200 Mg, Once/Single		Novartis
	Milrinone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187097	EXPEDITED (15-DAY)		OT	IR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-258431		38 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Vancomycin Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Kaletra	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187266	EXPEDITED (15-DAY)		OT	CA-ACCORD-196447			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Accord
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zoster Vaccine Solution For Injection			S	Subcutaneous	Subcutaneous		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cortisone			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187269	EXPEDITED (15-DAY)		OT	CA-ACCORD-196249		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel	Methotrexate			S	Unknown			Accord

Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide	S	Unknown	1 Every 1 Days		Not Reported
	Orencia	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	S	Oral	1 Every 12 Hours		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide	S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate	S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18188635	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-258095		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Chorioretinitis	Prednisone			S	Unknown	Unk		Mutual
	Prednisone			S				Mutual
	Prednisone			S				Mutual
	Mycophenolate			S	Unknown	Unk		Not Reported
	Mycophenolate			S				Not Reported
	Mycophenolate			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Hydroxychloroquine			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18189022	EXPEDITED (15-DAY)		OT	IR-SUN PHARMACEUTICAL INDUSTRIES LTD-		42 YR	Female	IRN

2020RR-258417

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphocyte Count Decreased; Multiple Sclerosis Relapse; Off Label Use; Uhthoff'S Phenomenon	Fingolimod			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Oseltamivir			S	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	1 Gram, Daily For 3 Consecutive Days		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18189758	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-066577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	567 Milligram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18189979	EXPEDITED (15-DAY)		DE, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-		67 YR	Female	ITA

BMS-2018-125402

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Not Reported
	Influenza Vaccine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191256	DIRECT		OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Substitution Issue	Hydroxychloroquine			S	Oral	Quantity:180 Tablet(S);	5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191532	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-26434			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gamastan		S	Intravenous (not otherwise specified)	Liquid Intramuscular	Not Reported
	Humira		S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Naproxen		S	Unknown	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	12985318	EXPEDITED (15-DAY)		OT	CA-ROCHE-1859492		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Amitriptyline Hydrochloride	S	Unknown	Not Reported
Amitriptyline Hydrochloride	S	Unknown	Not Reported
Arava	C		Not Reported
Calcium Carbonate	C		Not Reported
Cymbalta	C		Not Reported
Elavil (Canada)	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Imitrex	C		Not Reported
Lyrica	C		Not Reported
Plaquenil	C	Unknown	Not Reported
Premarin	C		Not Reported
Tenormin	C		Not Reported
Xeljanz	C		Not Reported
Acetaminophen	C		Not Reported
Amitriptyline	C		Not Reported
Sumatriptan	C		Not Reported
Sumatriptan Succinate	C		Not Reported
Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	13058057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015766		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk (Dutaion: 365 Unspecified Unit)		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Arthritis	Rituxan	S	Intravenous (not otherwise specified)	(Duration: 411 Units Unspecified)	Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	13153188	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005845		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, 4 Months		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram,1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, 17 Days	Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Bid	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Furosemide [Furosemide Sodium]	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Nifedipine	C	Unknown	Unk	Not Reported
	Palafer	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported
	Zinc Citrate	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported

Prednisone	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	5 Milligram, Qd		Not Reported
Prednisone	C	Unknown	10 Milligram, Bid		Not Reported
Toloxin [Digoxin]	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	500 Milligram, Qd		Not Reported
Leflunomide	C	Unknown	20 Milligram, Qd		Not Reported
Atorvastatin Calcium	C	Unknown	Unk		Not Reported
Tocilizumab	C	Unknown	Unk		Not Reported
Gold	C	Unknown			Not Reported
Lyrica	C	Unknown	75 Milligram, Qd		Not Reported
Trazodone	C	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	16082161	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported

	Methotrexate		S	Unknown	Unknown	Not Reported
	Plaquenil		S	Unknown	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	16689275	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	16778722	EXPEDITED (15-DAY)		DS, HO, OT	CA-ADVANZ PHARMA-GSH201706-003601			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	200 Mg, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Actemra			S	Unknown	680 Mg, Monthly		Not Reported
	Actemra			S	Unknown	360 Mg, Monthly		Not Reported
	Actemra			S	Unknown	380 Mg, Unknown		Not Reported

Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Pruritus; Rash; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	360 Mg, Monthly	Not Reported
	Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Freq: 2 X 1 Week	Not Reported
	Enbrel	S	Unknown	50 Mg, Freq: 2 X 1 Week, Biw	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	40 Mg, Freq: 1 X 2 Weeks, Qow	Not Reported
	Humira	S		40unk, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg Qow	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg	Not Reported
	Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S	Unknown	12.5 Mg,Q4w	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported

Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12 Mg	Not Reported
Methotrexate	S	Oral	10 Mg Q4w	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	17.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	15 Mg Q4w	Not Reported
Methotrexate	S	Unknown	12 Mg Q4w	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg Q4w	Not Reported
Methotrexate	S	Unknown	17 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Unk, Q4w	Not Reported
Arava	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Unknown	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Powder And Solvent For Intravesical Suspension	Not Reported
Remicade	S	Unknown	Unk, Powder And Solvent For Intravesical Suspension	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly Strength :50 Mg/Ml	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Monthly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Qow	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Tocilizumab	S	Unknown	680 Mg Q4w	Not Reported
Ciclosporin	C		Unk	Not Reported
Prednisolone	C			Not Reported
Prednisone	C		Unk	Not Reported
Prednisone	C		Unk	Not Reported
Xeljanz	C			Not Reported
Alendronate Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	17466730	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06445			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	17640700	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA087400			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Infection; Inflammation; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate			S	Other	1200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Sanofi
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			S	Other	2 Df Bag		Not Reported
	Paracetamol			C	Other	4 G, Qd		Not Reported
	Paracetamol			C				Not Reported
	Lasilix [Furosemide]			C	Other	30 Mg, Qd		Not Reported
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Doliprane			C				Not Reported
	Doliprane			C				Not Reported
	Diffu K			C	Other	3.6 G, Qd		Not Reported
	Diffu K			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	17810098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599567		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Deformity; Drug Ineffective; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Adalimumab	S	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 05 Years	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 09 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 15 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18061664	EXPEDITED (15-DAY)		OT	NVSC2020BR206556			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine	S	Transplacental	Unk	Novartis
	Betamethasone	S	Transplacental	Maternal Dose: 12 Mg/Day For 2 Days	Not Reported
	Azithromycin	S	Transplacental	Unk	Not Reported
	Methyldopa	S	Transplacental	Maternal Dose: 1 G/Day From 13 Weeks Of Gestation	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18131319	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020300261		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Dislocation; Purpura; Rash Pustular; Suspected Covid-19	Xeljanz Xr			S		11 Mg, Daily		Pfizer
	Centrum			S		Unk, 1x/Day		Pfizer
	Xanax			S		0.5 Mg, 2x/Day		Pfizer
	Doxycycline Monohydrate			S		100 Mg, 1x/Day		Pfizer
	Levetiracetam			S		750 Mg (500 Mg, One And Half Tablet), 3x/Day		Pfizer
	Pregabalin			S		150 Mg, 2x/Day		Pfizer
	Spironolactone			S		1 Tablet, 1x/Day		Pfizer
	Alphagan P			S		Unk		Not Reported
	Clonazepam			S		1 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported
	Lexapro			S		20 Mg, 1x/Day		Not Reported
	Methocarbamol			S		500 Mg, 2x/Day		Not Reported
	Naproxen			S		500 Mg, As Needed		Not Reported
	Rivastigmine			S		1 Patch, Daily (Every 24 Hours)		Not Reported
	Tizanidine			S		4 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18164948	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-002747			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Disorientation; Headache; Herbal Interaction; Hyperhidrosis; Musculoskeletal Pain; Seizure; Somnolence	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Celestial Sleepytime			S	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18181219	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3535222-00		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Reaction	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18189748	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025537			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab (Unknown)			S	Unknown			Not Reported
	Doxycycline			S	Unknown	50 Mg		Not Reported
	Doxycycline			S	Unknown	50 Mg		Not Reported
	Doxycycline Hyclate			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Leflunomide	S	Unknown	20 Mg, Daily		Not Reported
Methotrexate	S	Oral	4 Df, 1/Week		Not Reported
Methotrexate	S	Oral	4 Df, 1/Week		Not Reported
Methotrexate	S	Oral	4 Df, 1/Week		Not Reported
Methotrexate	S	Unknown	25 Mg		Not Reported
Methotrexate	S	Unknown	25 Mg		Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous	50 Mg, Monthly		Not Reported
Celebrex	C	Unknown			Not Reported
Prednisone	C	Unknown	25 Mg, Daily		Not Reported
Prednisone	C	Unknown	24 Mg, Daily		Not Reported
Prednisone	C	Unknown	10 Mg, Daily		Not Reported
Prednisone	C	Unknown	23 Mg, Daily		Not Reported
Sulfasalazine	C	Unknown			Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown			Not Reported
Tylenol Arthritis	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18189877	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05023		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Single		Lupin
	Azithromycin			S	Oral	500 Milligram, Qd		Lupin

Azithromycin	S	Oral	250 Milligram, Qd		Lupin
Hydroxychloroquine	S	Oral	400 Milligram, Bid (For Two Doses)		Lupin
Hydroxychloroquine	S	Oral	200 Milligram, Bid		Lupin
Methylprednisolone	S	Intravenous (not otherwise specified)	40 Milligram, Bid		Lupin
Betamethasone	S	Intramuscular	12 Milligram (2 Doses 24 Hours Apart)		Lupin
Lovenox [Enoxaparin Sodium]	S	Unknown	40 Milligram, Qd		Not Reported
Augmentine [Amoxicillin;Clavulanic Acid]	S	Oral	875 Milligram, Bid		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	800 Milligram, Single		Not Reported
Heparin	S	Unknown	Unk, Drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18190047	EXPEDITED (15-DAY)		HO	FR-BAXTER-2020BAX009350		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Infection	Endoxan 50 Mg, Comprime Enrobe			S	Oral			Baxter
	Plaquenil			S	Oral			Not Reported
	Fludara			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18190470	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-04996		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Ceftriaxone			S	Unknown	2 Gram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Lopinavir + Ritonavir			C	Unknown	200/50mg , Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18190513	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05009		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	800 Milligram (Loading Dose)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18190518	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05007		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	800 Milligram, Qd (Loading Dose)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Qd		Lupin
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Unfractionated Heparin			C	Unknown	Unk (Continuous Infusion)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18190520	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05008		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Ceftriaxone		S	Intravenous (not otherwise specified)	1 Gram, Bid	Lupin
	Hydroxychloroquine		S	Unknown	800 Milligram, (Loading Dose)	Lupin
	Hydroxychloroquine		S	Unknown	400 Milligram, Qd	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18190521	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05010		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Milligram, Qd		Lupin
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	800 Milligram (Loading Dose)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191119	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1817559			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Naproxen	S	Unknown	100 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191303	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX016778		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form: Not Specified		Baxter
	Azathioprine			S	Unknown	Dosage Form: Tablet		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown	Dosage Form: Not Specified		Not Reported
	Codeine			C	Unknown			Not Reported
	Arava			C	Unknown	Dosage Form: Tablet		Not Reported
	Fentanyl			C	Unknown	Dosage Form: Not Specified		Not Reported
	Levofloxacin			C	Unknown	Dosage Form: Not Specified		Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191546	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05072		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ibrutinib			C	Unknown	420 Milligram, Qd		Not Reported
	Ibrutinib			C	Unknown	140 Milligram, Qd		Not Reported
	Ibrutinib			C	Unknown	420 Milligram, Qd		Not Reported
	Tocilizumab			C	Unknown	400 Milligram, Unk		Not Reported
	Immunoglobulins Nos			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191724	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05051		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Tobramycin			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ribavirin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Lupin
	Vancomycin			S	Oral	Unk		Lupin
	Fluconazole			C	Unknown	Unk		Not Reported
	Apixaban			C	Unknown	Unk (5 Milligram)		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported

	Piperacillin & Tazobactam	C	Unknown	Unk		Not Reported
	Nitroglycerin	C	Topical	Unk		Not Reported
	Lopinavir + Ritonavir	C	Unknown	Unk		Not Reported
	Heparine [Heparin]	C	Intracardiac	Unk		Not Reported
	Heparine [Heparin]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191725	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05080		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191867	EXPEDITED (15-DAY)		HO, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-257771		65 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191895	NON-EXPEDITED			US-TEVA-2020-US-1818016		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191899	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-066721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Bupropion	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191908	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-066802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191916	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-066698		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not	8 Milligram, Qmo		Not Reported

			otherwise specified)		
	Arava	S	Oral	10 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191917	EXPEDITED (15-DAY)		OT	CA-ACCORD-197378		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Accord
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18191993	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-26596			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab		S	Unknown		Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Anakinra		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Naproxen		S	Unknown	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192903	EXPEDITED (15-DAY)		OT	NVSC2020SE231894			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Ocular Icterus; Pruritus; Yellow Skin	Azitromycine			S	Unknown	500 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Zink			S	Unknown	120 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18193519	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1073414		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Haemothorax; Heparin-Induced Thrombocytopenia; Off Label Use; Respiratory Failure	Heparin	S	Unknown			Mylan
	Heparin	S				Mylan
	Hydroxychloroquine	S	Unknown			Mylan
	Azithromycin	S	Unknown			Mylan
	Lovenox	S	Unknown			Mylan
	Lovenox	S				Mylan
	Tocilizumab	S	Unknown	One Dose		Not Reported
	Solumedrol	C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18193531	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020325265		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Off Label Use; Product Use In Unapproved Indication	Tazocilline			S	Intravenous drip	Unk		Pfizer
	Azithromycin			S	Oral	Unk		Pfizer
	Linezolid			S	Intravenous drip	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Tienam			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18193895	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020325282		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Supraventricular Tachycardia	Zithromax			S	Oral	500 Mg Then 250 Mg		Pfizer
	Zithromax			S	Oral	500 Mg Then 250 Mg		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18194735	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1818280		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown	800 Milligram Daily; On The First Day		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily; For The Following 4 Days		Teva
	Tacrolimus			S	Unknown			Not Reported
	Chloroquine			S	Unknown	1000 Milligram Daily;		Not Reported
	Losartan			C	Unknown	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18195101	EXPEDITED (15-DAY)		LT	NVSC2020US234425		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Ceftriaxone			S	Intravenous (not otherwise specified)	500 Mg		Novartis
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Bid For Two Doses		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Bid For Eight Doses		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	125 Mg For One Dose		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Tapered Over 5 Days To 20mg Daily For One Dose		Not Reported
	Betamethasone			S	Intramuscular	12 Mg Single Dose Repeated For One Dose		Not Reported

24 Hours Later

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196043	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1817534		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196077	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1817524		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

	Orencia	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196096	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1817549		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Naproxen			S	Unknown	1500 Milligram Daily;		Teva
	Naproxen			S	Unknown	1500 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Synthroid			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196211	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1818148		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product	Oxycodone			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Actavis

Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Leflunomide	S	Oral	Barr
	Methotrexate	S	Unknown	Barr
	Oxycodone-Acetaminophen	S	Unknown	Actavis
	Sulfamethoxazole And Trimethoprim	S	Unknown	Teva
	Actemra	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Chlorhexidine	S	Topical	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Chlorhexidine Gluconate Oral Rinse	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortison (Cortisone)	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira (Adalimumab)	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Periogard Alcohol Free	S	Buccal	Not Reported
Plaquenil	S	Oral	Not Reported
Pseudoephedrine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathaladine	S	Oral	Not Reported
Sulfathaladine	S	Oral	Not Reported
Sulfathaladine	S	Unknown	Not Reported
Topicort	S	Cutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Atasol /00020001/	C		Not Reported
Cetirizine	C		Not Reported
Desogestrel/Ethinyl Estradiol	C		Not Reported
Ibuprofen	C		Not Reported
Pantoloc	C		Not Reported
Pantoprazole	C		Not Reported
Salazopyrin	C		Not Reported
Tylenol	C		Not Reported
Tylenol With Codeine	C		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18213508	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05070		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ibrutinib			C	Unknown	420 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	13852876	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069854		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actonel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported

Cyclobenzaprine	C	Unknown	10 Milligram		Not Reported
Desoximetasone	C	Unknown	5 Milligram		Not Reported
Desoximetasone	C	Unknown	5 Milligram, Qd		Not Reported
Prednisone Acetate	C	Unknown	5 Milligram, Qd		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	14235002	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

					otherwise specified)					
	Rituximab			S	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	15933878	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656787-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	16156007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728799-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intramuscular			Not Reported
	Actemra			S	Unknown			Not Reported

Sleep Disorder; Synovitis; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Septra	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	16825327	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	16878971	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2569757-00		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Apo Hydroxyquine	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	17332071	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-01520		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Unknown	Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown Solution Subcutaneous. Single Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported

Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Myochrysine	S	Intramuscular	(Solution)	Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported

Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Celebrex	S	Unknown	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Fosamax	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported

Prednisolone	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	17751868	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020178146		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Amlor			S	Oral	1 Df, 1x/Day		Pfizer
	Augmentin [Amoxicillin Trihydrate;Clavulanate Potassium]			S	Intravenous (not otherwise specified)	3 G, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Colchimax (Colchicine\Papaver Somniferum Powder\Tiemonium Methylsulphate)			S	Oral	1 Df, 1x/Day		Not Reported
	Paracetamol			S	Oral	4 G, 1x/Day		Not Reported
	Arimidex			S	Oral	1 Mg, 1x/Day		Not Reported
	Nefopam Hydrochloride			S	Oral	80 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	17980827	EXPEDITED (15-DAY)		OT	CA-ACCORD-188321		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis;	Methotrexate			S	Subcutaneous			Accord
	Sulfasalazine			S				Not Reported

Sleep Disorder; Treatment Noncompliance	Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S			Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Arava	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18029273	EXPEDITED (15-DAY)		OT	BR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055308			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cholecystitis Chronic; Photosensitivity Reaction; Venous Thrombosis; Vomiting	Abatacept			S	Intravenous (not otherwise specified)	Three 250mg Vials Monthly		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18174555	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-196658		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis Crisis; Off Label Use	Hydroxychloroquine			S		Via Og Tube		Not Reported
	Azithromycin			S				Not Reported
	Immunoglobulins			C	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			C				Not Reported
	Hydroxychloroquine			S		Via Og Tube		Not Reported

	Azithromycin	S	Via Og Tube	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18194741	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04968		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Aspirine			C	Unknown	81 Milligram, Qd		Not Reported
	Clopidogrel			C	Unknown	75 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18194795	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-05033		60 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Sulfamethoxazole And Trimethoprim Tablet			S	Unknown	1 Dosage Form, Bid (400/80)		Novel Labs
	Meropenem			C	Intravenous (not otherwise specified)	1 Gram, Tid (Q.8h)		Not Reported
	Tacrolimus			C	Unknown	2 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	15 Milligram, Qd		Not Reported
	Folic Acid			C	Unknown	1 Milligram, Qd		Not Reported
	Ursodeoxycholic Acid			C	Unknown	900 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18194847	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-05034		46 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine		S	Unknown	400 Milligram, Qd	Lupin
	Tacrolimus		C	Unknown	3 Gram, Tid	Not Reported
	Prednisolone		C	Unknown	1 Milligram, Qd	Not Reported
	Folic Acid		C	Unknown	1 Milligram, Qd	Not Reported
	Aspirine		C	Unknown	80 Milligram, Qd	Not Reported
	Mycophenolate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18194877	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-044473		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Vancomycin			S	Unknown	Unk		Aurobindo
	Vancomycin			S				Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18194907	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-04993		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18195555	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025541			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Rituximab (Unknown)	S	Unknown	Unk	Not Reported
	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	9 Mg	Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	9 Mg	Not Reported
	Enbrel	S	Unknown	50 Mg, 1 Every 1 Weeks	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Humira	S	Subcutaneous	50 Mg	Not Reported
	Humira	S			Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	9 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	9 Mg	Not Reported
	Infliximab	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Leflunomide	S	Unknown	20 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	20 Mg	Not Reported
	Methotrexate	S	Unknown	20 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, 1 Every 1 Weeks	Not Reported
	Prednisone	S	Unknown	9 Mg	Not Reported
	Simponi	S	Subcutaneous	Unk, 1 Every 1 Months	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Acetaminophen	C	Unknown	500 Mg	Not Reported
	Cetirizine Hydrochloride	C	Unknown	10 Mg. 1 Every 1 Days	Not Reported

	Gabapentin		C	Unknown	600 Mg, 3 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18195561	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA025599			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown	12.5 Mg, 1 Every 2 Days		Not Reported
	Remicade			S	Unknown			Not Reported
	Statex [Morphine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18195730	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202008008049			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Disorder; Drug Ineffective; Drug-Induced Liver Injury; Fatigue; Gait Disturbance; Inflammation; Insomnia; Multiple Fractures; Musculoskeletal Stiffness; Nausea; Nephropathy	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported

Toxic

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18195824	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-038247		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Function Test Abnormal	Azithromycin			S	Oral	500mg Dosis Choque Y 250 Mg C/24h Mantenimiento		Aurobindo
	Azithromycin			S				Aurobindo
	Remdesivir			S	Intravenous drip	100 Milligram, Once A Day		Not Reported
	Remdesivir			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	6 Milligram, Once A Day		Not Reported
	Dexamethasone			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Midazolam			C	Unknown	Unk		Not Reported
	Fentanyl			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Cisatracurium			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Enalapril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18195932	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025596			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis	Rituximab (Unknown)	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	3 Mg, 1 Every 1 Days	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	50 Milligram	Not Reported
	Prednisone	S	Oral	3 Milligram, 1 Every 1 Days	Not Reported
	Prednisone	S	Unknown	50 Milligram	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	3 Mg, 1 Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18195996	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Fatigue; Glossodynia; Hand Deformity; Hip	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex

Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Leflunomide	S	Oral	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Reactine /00884302/	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Fosamax	C	Unknown	Unk	Not Reported
	Reactine /00884302/	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196057	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2020-05062		88 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196207	EXPEDITED (15-DAY)		OT	CA-ACCORD-197234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Encephalitis; Meningitis; Synovitis	Methotrexate			S	Unknown			Accord
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196220	EXPEDITED (15-DAY)		DS	CA-ACCORD-197240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Methotrexate		S	Unknown		Accord
	Acetaminophen		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Indometacin/Indometacin Meglumine/Indometacin Sodium/Indometacin Sodium Trihydrate/Indometacin Tropi		S	Unknown		Not Reported
	Morphine		S	Unknown		Not Reported
	Prednisone		S	Unknown	1 Every 1 Days	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196238	EXPEDITED (15-DAY)		OT	CA-ACCORD-197242			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Hydroxychloroquine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196318	EXPEDITED (15-DAY)		DE, HO, OT	US-TEVA-2020-US-1818525		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Multiple Organ Dysfunction Syndrome; Off Label Use; Pneumonia	Ciclosporin			S	Unknown	350 Milligram Daily;		Ivax
	Ciclosporin			S				Ivax
	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S				Not Reported
	Pyridostigmine			C	Unknown			Not Reported
	Immune-Globulin			C	Intravenous (not otherwise specified)	2g/Kg		Not Reported
	Immune-Globulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196325	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025615			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown	100.0 Mg		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg		Not Reported
	Methotrexate			S	Unknown	25.0 Mg		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	500.0 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196362	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202008008108			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pain In Extremity; Subclavian Vein Thrombosis; Swelling	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Lantus			S	Unknown	Unk		Not Reported
	Apidra			S	Unknown	Unk		Not Reported
	Levosert			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196413	EXPEDITED (15-DAY)		OT	CA-ACCORD-197077		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196453	EXPEDITED (15-DAY)		DS	CA-ACCORD-197126		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability;	Methotrexate			S	Unknown	Not Specified		Accord

Drug Ineffective; Hepatic Enzyme Increased; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Intravenous drip			Not Reported
	Sulfasalazine	S	Unknown	Not Specified		Not Reported
	Prednisone	C		Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196459	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-197124		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Musculoskeletal Disorder	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196541	EXPEDITED (15-DAY)		OT	ID-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-258328		29 YR	Male	IDN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	500 Milligram, Daily		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Ipca
	Oseltamivir			S	Unknown	75 Milligram, Bid		Not Reported
	Vitamin C			C	Unknown	1000 Milligram, Tid		Not Reported

	Vitamin D			C	Unknown	5000 International Unit, Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196609	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05052		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Vancomycin			S	Oral	Unk		Lupin
	Ribavirin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Lupin
	Cefdinir			S	Unknown	Unk		Lupin
	Nitroglycerin			C	Topical	Unk		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported
	Lopinavir + Ritonavir			C	Unknown	Unk		Not Reported
	Cefepime			C	Intracardiac	Unk		Not Reported
	Heparin			C	Unknown	25000 Unit Heparin Drip At 11u/Kg/Hour		Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196612	EXPEDITED (15-DAY)		OT	ID-LUPIN PHARMACEUTICALS INC.-2020-05081		29 YR	Male	IDN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd (Day 4)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Oseltamivir			S	Unknown	75 Milligram, Bid		Lupin

Vitamin D [Colecalciferol]	C	Unknown	5000 International Unit, Qd (Scheduled For 14 Days)		Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	1000 Milligram, Tid (Three Times Daily; Scheduled For 14 Days)		Not Reported
Paracetamol	C	Oral	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196651	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201812-004112			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Retinal Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Prednisolone			C		Unk		Not Reported
	Gaster D			C		Unk		Not Reported
	Lunesta			C		Unk		Not Reported
	Halcion			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196777	EXPEDITED (15-DAY)		DE, OT	BR-LUPIN PHARMACEUTICALS INC.-2020-05094		60 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Sodium Bicarbonate			C	Unknown	20 Milliliter		Not Reported
	Sodium Bicarbonate			C	Unknown	250 Milliliter		Not Reported
	Atropine			C	Unknown	1 Milligram, Two Vials Of Atropine 1 Mg; 8 Vials Of Atropine At Percutaneous Pacemaker Insertion		Not Reported
	Atropine			C				Not Reported

Meropenem	C	Unknown	Unk	Not Reported
Micafungin	C	Unknown	Unk	Not Reported
Metamizole	C	Unknown	Unk	Not Reported
Immunoglobulin Human	C	Unknown	Unk	Not Reported
Insulin	C	Unknown	Unk	Not Reported
Norepinephrine	C	Unknown	Initial Indication Not Stated; Was Increased To 12 Ml/H On 11 April 2020	Not Reported
Norepinephrine	C	Unknown	At 100 Ml/H At The Moment Of The Cp Arrest	Not Reported
Norepinephrine	C	Unknown	15 Ml/H After Cp Arrest	Not Reported
Norepinephrine	C	Unknown	Increasing Norepinephrine Up To 40 Ml/H	Not Reported
Dexmedetomidine	C	Unknown	Unk	Not Reported
Epinephrine	C	Unknown	1 Milligram, 2 Vials Of Epinephrine 1 Mg; 3 Vials Of Epinephrine At Percutaneous Pacemaker Insertion	Not Reported
Epinephrine	C			Not Reported
Fentanyl	C	Unknown	Unk	Not Reported
Heparin	C	Unknown	Unk	Not Reported
Amiodarone	C	Unknown	300 Milligram, , Loading Infusion Was Administered In 20 Min. And A Maintenance Infusion Was Continu	Not Reported
Amiodarone	C			Not Reported
Dobutamine	C	Unknown	6 Microgram/Kilogram	Not Reported
Saline [Sodium Chloride]	C	Unknown	1500 Milliliter	Not Reported
Tocilizumab	C	Unknown	400 Milligram	Not Reported
Metformin	C	Unknown	1 Dosage Form, Qd	Not Reported
Insulin Glulisine	C	Unknown	Unk	Not Reported

	Gabapentin		C	Unknown	Unk	Not Reported
	Calcium Gluconate		C	Unknown	Unk	Not Reported
	Teicoplanin		C	Unknown	Unk	Not Reported
	Etomidate		C	Unknown	Unk	Not Reported
	Sodium Gluconate		C	Unknown	30 Milliliter	Not Reported
	Midazolam		C	Unknown	Unk	Not Reported
	Furosemide		C	Unknown	Unk	Not Reported
	Lidocaine		C	Unknown	Unk	Not Reported
	Losartan		C	Unknown	Unk	Not Reported
	Hydrocortisone		C	Unknown	Unk	Not Reported
	Piperacillin/Tazobactam		C	Unknown	Unk	Not Reported
	Cisatracurium Besilate		C	Unknown	Unk	Not Reported
	Enoxaparin Sodium		C	Unknown	Unk	Not Reported
	Amoxicillin/Clavulanic Acid		C	Unknown	Unk	Not Reported
	Rocuronium		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196883	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05037		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Betamethasone			S	Intravenous (not otherwise specified)	12 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram		Lupin
	Darunavir And Cobicistat			S	Unknown	800 Milligram, Qd, For 5 Days		Not Reported
	Remifentanil			S	Unknown	50-100ng/Kg/Min		Not Reported
	Cisatracurium			S	Unknown	2-3microgram/Kg/Min		Not Reported
	Enoxaparin			S	Unknown	Unk		Not Reported
	Piperacilline/Tazobactam			S	Unknown	Unk		Not Reported

	Midazolam	S	Unknown	3-8mg/H		Not Reported
	Paracetamol	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18196902	EXPEDITED (15-DAY)		OT	CA-ACCORD-197211		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S				Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197294	EXPEDITED (15-DAY)		OT	CA-ACCORD-197109		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Treatment Failure; Weight Decreased	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197295	EXPEDITED (15-DAY)		OT	CA-ACCORD-197102		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug	Methotrexate			S				Accord

Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Insomnia; Iodine Allergy; Pain; Product Use Issue; Rheumatoid Arthritis	Simponi		S	Subcutaneous		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine		S			Not Reported
	Enbrel		S			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride		S		1 Every 1 Days	Not Reported
	Statex		C			Not Reported
	Morphine		C			Not Reported
	Morphine		C			Not Reported
	M-Eslon		C		2 Every 1 Days	Not Reported
	Folic Acid		C		1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197305	EXPEDITED (15-DAY)		OT	CA-ACCORD-197140		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S				Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197306	EXPEDITED (15-DAY)		OT	CA-ACCORD-197139		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased;	Methotrexate			S		1 Every 1 Weeks		Accord

Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Enbrel	S			Not Reported
	Arava	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197315	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-197121		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Arthralgia; Chills; Diarrhoea; Drug Ineffective; Fatigue; Heart Rate Increased; Liver Function Test Increased; Nausea; Ovarian Cyst; Ovulation Pain; Pain; Pyrexia; Quality Of Life Decreased; Rash; Uterine Cyst; Vomiting; Wheelchair User; White Blood Cell Count Increased	Methotrexate			S				Accord
	Benadryl			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Synthroid			S				Not Reported
	Paracetamol			C	Oral			Not Reported
	Cimzia			C				Not Reported
	Cortisone			C				Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Plaquenil			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197325	EXPEDITED (15-DAY)		HO	CA-ACCORD-197157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Golimumab			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Certolizumab Pegol			C		Solution Subcutaneous ,Single Use		Not Reported
	Etanercept			C				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197326	EXPEDITED (15-DAY)		OT	CA-ACCORD-197159			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate			S				Accord
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S				Not Reported
	Prednisone			C				Not Reported
	Citalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197330	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-197376		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Aclasta			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tramacet			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Metformin			C	Unknown			Not Reported
	Calcium Carbonate/Calcium Lactogluconate			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Prednisone			C	Unknown	Not Specified		Not Reported
	Premarin			C	Unknown			Not Reported
	Risedronic Acid			C	Unknown	1 Every 1 Weeks		Not Reported
	Depo-Medrol			C	Intramuscular			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Oxycodone Hydrochloride/Paracetamol			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Depo-Medrol	C	Subcutaneous	1 Every 1 Months, Suspension Intra- Articular	Not Reported
	Enbrel	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methylprednisolone	C	Intramuscular	1 Every 1 Months	Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Nortriptyline	C	Unknown	1 Every 1 Days	Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Unknown	1 Every 1 Weeks	Accord
	Methotrexate	S	Unknown		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197337	EXPEDITED (15-DAY)		OT	CA-ACCORD-197189		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Methotrexate			S	Unknown			Accord
	Metaraminol			S	Unknown			Not Reported

Humira	S	Subcutaneous	1 Every 2 Weeks		Not Reported
Hydroxychloroquine	S	Unknown	1 Every 24 Hours		Not Reported
Orencia	S	Unknown			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197338	EXPEDITED (15-DAY)		OT	CA-ACCORD-197187		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Accord
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197342	EXPEDITED (15-DAY)		OT	CA-ACCORD-197273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S				Accord
	Apo-Leflunomide			S				Not Reported
	Hydroxychloroquine			S		Frequency: 1 Every 24 Hours		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		Frequency: 4 Every 1		Not Reported

				Days	
	Paracetamol	C			Not Reported
	Hydrocortisone	C			Not Reported
	Hydromorphone/Hydromorphone Hydrochloride	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Lyderm	C			Not Reported
	Naproxen	C			Not Reported
	Sodium Aurothiomalate	C			Not Reported
	Prednisone	C		Frequency: 1 Every 24 Hours	Not Reported
	Naproxen	C		Frequency: 1 Every 24 Hours	Not Reported
	Sodium Aurothiomalate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197344	EXPEDITED (15-DAY)		OT	CA-ACCORD-197272			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate			S				Accord
	Etanercept			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197397	EXPEDITED (15-DAY)		HO, OT	TR-IPCA LABORATORIES LIMITED-IPC-2020-TR-002827			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose; Bradycardia; Electrocardiogram Qt Prolonged; Medication Error	Hydroxychloroquine		S	Oral	200 Milligram, Bid	Ipca
	Hydroxychloroquine		S	Oral	1600 Milligram	Ipca
	Oseltamivir		C	Oral	75 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197538	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-067218		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198437	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1073987		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Drug Interaction; Drug Level Increased; Haematocrit Decreased; Haemoglobin Decreased; Off Label Use; Oral Herpes	Lopinavir/Ritonavir			S	Unknown	Unk, Bid 200mg/50mg Two Tablets Twice Daily		Mylan
	Enoxaparin			S	Unknown	6000 International Unit		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Ruxolitinib			S	Unknown	5 Milligram2 Tablets/Day For 3 Days		Mylan
	Ruxolitinib			S	Unknown	10 Milligram Dose Doubled		Mylan
	Ruxolitinib			S	Unknown	5 Milligram, Qd		Mylan
	Levothyroxine			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198501	EXPEDITED (15-DAY)		OT	NVSC2020US232619		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Use In Unapproved Indication; Rash; Renal Injury	Hydroxychloroquine			S	Unknown	Unk, 5-Day Course		Novartis
	Azithromycin			S	Unknown	Unk, 5-Day Course		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Piperacillin Sodium,Tazobactam Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198547	EXPEDITED (15-DAY)		HO	BE-MYLANLABS-2020M1074133		50 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Off Label Use	Azithromycin			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Heparin			C	Unknown	At Admission		Mylan
	Propofol			C	Unknown	At Admission		Mylan
	Clonidine			C	Unknown	At Admission		Mylan
	Norepinephrine			C	Unknown	At Admission		Mylan
	Sufentanil			C	Unknown	At Admission		Mylan
	Rocuronium			C	Unknown	At Admission		Mylan
	Pantoprazole			C	Unknown	Started 9 Days Before Onset Of Symptoms		Mylan
	Sevoflurane			C	Unknown	Started 8 Days Before Onset Of Symptoms		Mylan
	Cefuroxime			C	Unknown	Started 6 Days Before Onset Of Symptoms		Mylan
	Flucloxacillin			C	Unknown	Started 4 Days Before Onset Of Symptoms		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198789	EXPEDITED (15-DAY)		DE, OT	US-TEVA-2020-US-1818271		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Haematuria; Nephropathy Toxic; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram Daily; 4.2mg/Kg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198818	EXPEDITED (15-DAY)		OT	CA-ACCORD-196989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral	1 Every 1 Days		Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Enbrel			S		1 Every 1 Weeks		Not Reported
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198819	EXPEDITED (15-DAY)		OT	CA-ACCORD-196991		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate	Methotrexate			S	Parenteral	1 Every 1 Weeks		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Increased; Urticaria	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Actemra	C	Unknown		Not Reported
	Methotrexate	S	Oral	1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198822	EXPEDITED (15-DAY)		OT	CA-ACCORD-196994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Unknown			Not Reported
	Arava			S	Oral	2 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	3 Every 1 Weeks		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Arava			S	Oral	2 Every 1 Weeks		Not Reported

	Enbrel	S	Unknown	1 Every 1 Weeks		Not Reported
	Methotrexate	S	Intramuscular			Not Reported
	Methotrexate	S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198826	EXPEDITED (15-DAY)		OT	CA-ACCORD-196996			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198835	EXPEDITED (15-DAY)		OT	CA-ACCORD-197281			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Methotrexate			S	Unknown	Not Specified		Accord
	Celebrex			S	Oral	2 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution		Not Reported

			Intravenous		
Rituximab	S	Unknown			Not Reported
Sulfasalazine	S	Oral	2 Every 1 Days		Not Reported
Arava	S	Unknown			Not Reported
Xeljanz	S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18199048	EXPEDITED (15-DAY)		DS	CA-ELI_LILLY_AND_COMPANY-CA202008006992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Arava			S	Unknown	Unk, Unknown		Not Reported
	Baclofen			S	Unknown	Unk, Unknown		Not Reported
	Humira			S	Subcutaneous	Unk, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unknown		Not Reported
	Lyrica			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unknown		Not Reported
	Celebrex			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18199056	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA202008006531		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unknown		Not Reported
	Metformin Hydrochloride			S	Unknown	Unk, Unknown		Not Reported
	Metformin Hydrochloride			S				Not Reported
	Prednisone			S	Unknown	Unk, Unknown		Not Reported

Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Thrombosis; Uterine Disorder	Rituximab	S	Intravenous (not otherwise specified)	100 Mg, Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unk, Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Unk, Unknown	Not Reported
	Azathioprine	C			Not Reported
	Methotrexate	C			Not Reported
	Xarelto	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18199202	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2020325234		50 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use; Oxalosis; Product Use In Unapproved Indication; Toxicity To Various Agents	Azithromycin			S		500 Mg, Daily		Pfizer
	Hydroxychloroquine			S		400 Mg, Twice Daily		Not Reported
	Lopinavir/Ritonavir			S		1 Df, Daily		Not Reported
	Darunavir And Cobicistat			S		1 Df, Daily		Not Reported
	Tocilizumab			S	Subcutaneous	Unk, Single		Not Reported
	Tocilizumab			S				Not Reported
	Vitamin C [Ascorbic Acid]			S	Intravenous (not otherwise specified)	50 Mg/Kg, Four Times Daily (High-Dose)		Not Reported
	Meropenem			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18199762	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-067453		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Sleep Disorder; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Unknown			Not Reported
Myochrysine	S	Intramuscular			Not Reported
Celebrex	C	Unknown	200 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18199809	EXPEDITED (15-DAY)		OT	NVSC2020US233708			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk, Maternal Dose Unk		Novartis
	Azithromycin			S	Transplacental	Unk, Maternal Dose Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201106	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-26471			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not			Not Reported

Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting				otherwise specified)			
	Prednisone		S	Oral			Not Reported
	Sulfasalazine		S	Oral			Not Reported
	Triamcinolone		S	Unknown	Unknown		Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201115	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-26356		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Etanercept			S	Unknown	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Oral	Unknown		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	Unknown		Not Reported
	Ferrous Gluconate			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported
	Lasix [Furosemide]			C	Unknown	Unknown		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201116	EXPEDITED (15-DAY)		DS, HO	CA-SAMSUNG BIOEPIS-SB-2020-26369			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	12769886	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076654		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired Gastric Emptying; Influenza; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia	S	Subcutaneous	125 Milligram Every 1 Week	Bristol Myers Squibb
	Actemra	S	Subcutaneous	Every 1 Week	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2 Times Every 1 Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Every 1 Week	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Every 1 Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Gold	S	Intramuscular	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20.0 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Meloxicam	C	Oral	7.5 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	12929734	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091804			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Methadone			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported

Ramipril	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Topical	Eye Drops, Bid	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Milligram, Qd	Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Baclofen	C	Unknown	10 Milligram, Bid	Not Reported
Levaquin	C	Unknown	500 Milligram, Qd	Not Reported
Calcium	C	Unknown	500 Milligram, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk, Qwk	Not Reported
Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
Estrogel	C	Unknown	1 Dosage Form, Qd	Not Reported
Estradiol	C	Unknown	0.6 Percent, Tid	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Zingiber Officinale	C	Oral	500 Milligram, Prn	Not Reported
Calcium Gluconate	C	Unknown		Not Reported
Gravol Ginger Nighttime	C	Oral	500 Milligram, Prn	Not Reported
Xalatan	C	Unknown	50 Milligram, 1 Every 1 Day	Not Reported
Xalatan	C	Unknown	5 Milligram, 1 Every 1 Day	Not Reported
Xalatan	C	Unknown	50 Microgram, Qd	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	14535486	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BIOVITRUM-2018CA0124		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cardiac Disorder; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo Sulfasalazine Tab 500mg			S				Not Reported
	Apo Sulfasalazine Tab 500mg			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

		otherwise specified)	
Rituxan	S	Unknown	Not Reported
Rituxan	S		Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Ilaris Single-Use Vial	S	Unknown	Not Reported
Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
Gold	S	Unknown	Not Reported
Gold	S		Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Cannabis Sativa	S		Not Reported

Cannabis Sativa	S			Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Oxycodone	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S			Not Reported
Minocycline	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Xeljanz	S	Oral		Not Reported
Sulfasalazine	S	Unknown	Coated Tablet	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Marijuana	S	Unknown		Not Reported
Urelumab	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lyrica	C	Oral		Not Reported
Plaquenil	C	Unknown		Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Unknown		Not Reported
Rituximab	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C			Not Reported
Xeljanz	C	Oral		Not Reported

	Xeljanz	C	Unknown	Not Reported
	Kineret	C		Not Reported
	Lyrica	C	Oral	Not Reported
	Plaquenil	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	14539305	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	100 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	100 Milligram		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported

Gold	S	Intramuscular		Not Reported
Imuran	S			Not Reported
Leflunomide	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Methotrexate	S			Not Reported
Methotrexate	C	Oral		Not Reported
Methotrexate	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Desoximetasone	C	Unknown		Not Reported
Cortisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	15065862	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting;	Kineret			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S		12.5 Mg		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	70 Mg		Not Reported
	Immune Globulin (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	70 Gm		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown	5 Mg		Not Reported

Wheelchair User	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
	Apo-Triamcinolone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	15621393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557319-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	15651514	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-GLAXOSMITHKLINE-CA2015187246			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adjustment Disorder With Depressed Mood; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infection; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Range Of Motion Decreased; Joint	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Glaxosmithkline
	Cetirizine Hydrochloride			S	Oral	10 Mg		Glaxosmithkline
	Cetirizine Hydrochloride			S	Oral	25 Mg		Glaxosmithkline
	Zyrtec-D			S	Unknown	10 Mg, Unk		Glaxosmithkline
	Zyrtec-D			S				Glaxosmithkline
	Cirrus			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Subcutaneous	1 Mg		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Folic Acid			S	Oral	25 Mg		Glaxosmithkline
	Folic Acid			S	Oral	5 Mg, Unk		Glaxosmithkline
	Folic Acid			S	Unknown	5 Mg, Unk		Glaxosmithkline
	Folic Acid			S	Oral	500 Mg		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Acetaminophen			S	Oral	20 Mg		Glaxosmithkline
	Topicort			S	Cutaneous	Unk		Glaxosmithkline
	Topicort			S	Oral	Unk		Glaxosmithkline
	Topicort			S	Subcutaneous	Unk		Glaxosmithkline
	Cortisone Acetate			S	Oral	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	25 Milligram		Glaxosmithkline

Swelling; Memory Impairment; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Pericarditis; Prescribed Overdose; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Sleep Disorder; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Noncompliance; Type 2 Diabetes Mellitus; Vomiting; Walking Aid User; Weight Decreased; Wheezing; Wound; Wound Infection	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	1 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Xeljanz	S	Unknown	5 Mg, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	5 Mg, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk, Qd	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Dosage Form: Unspecified	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	Unk Milligram	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Apo-Prednisone	S	Unknown	1 Milligram	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	25 Mg, We	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	25 Mg, Qd (Unk Unk, 2x/Day (Bid))	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	1 Mg	Not Reported
Prednisone	S	Oral	5 Mg	Not Reported
Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported

Hydroxychloroquine	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Unknown	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Cutaneous	Unk	Not Reported
Topicort (Desoximetasone)	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Subcutaneous	Unk	Not Reported
Topicort (Desoximetasone)	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk(Cutaneous Route)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, 25 Milligram, Ointment	Not Reported
Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Controlled Release Tablets	Not Reported
Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S			Not Reported
Cortisone (Hydrocortisone)	S	Oral	Unk	Not Reported
Cortisone (Hydrocortisone)	S	Oral	Unk	Not Reported
Cortisone (Hydrocortisone)	S	Oral	Unk	Not Reported
Cortisone (Hydrocortisone)	S	Topical	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Glaxosmithkline

Ibuprofen	C	Unknown	Unk		Glaxosmithkline
Cholecalciferol	C	Unknown	Unk		Glaxosmithkline
Cholecalciferol	C	Unknown	Unk		Glaxosmithkline
Salazopyrin	C	Unknown	Unk		Not Reported
Atasol (Paracetamol)	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Prinivil	C	Unknown	Unk		Not Reported
Prinivil	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	15683294	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573840-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Bone Density Decreased; Cataract; Cataract; Contraindicated Product Administered; Diarrhoea; Diarrhoea; Dizziness; Dizziness; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Dry Eye; Fatigue; Fatigue; Feeling Abnormal; Feeling Abnormal; Fibromyalgia; Fibromyalgia; Hand Deformity; Hand Deformity; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Malaise; Malaise; Mobility Decreased; Mobility	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Diclofenac			C				Not Reported
	Depo-Medrol			C	Intra-arterial			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Pantoprazole Magnesium			C				Not Reported

Decreased; Muscular Weakness; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Myalgia; Myalgia; Off Label Use; Pain; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Pulmonary Toxicity; Pulmonary Toxicity; Rash Maculo-Papular; Rash Maculo-Papular; Rash Pruritic; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Lung; Synovial Cyst; Synovial Cyst; Synovitis; Synovitis; Tenosynovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Methylprednisolone Acetate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	15755439	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-2229884			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	15978705	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported

	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	16079906	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-05955		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin(Human)	S	Unknown	Unknown	Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Naproxen Sodium	S	Unknown	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Oral		Not Reported
Triamcinolone	S	Other	Unknown	Not Reported
Triamcinolone	S	Unknown	Unknown	Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Hexacetonide	S	Other	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported

Triamcinolone Acetonide	S	Intra-articular	Unknown, Suspension Intraarticular	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown, Suspension Intra Articular	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Gamastan	S	Intramuscular	Liquid Intramuscular	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral	Unknown	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Gammagard	S	Intravenous (not otherwise specified)		Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Unknown, Solution Intravenous	Not Reported
Gammagard	S			Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17306659	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004089		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Maternal Exposure During Pregnancy; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	3011.2 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2912.0 Milligram		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Ophthalmic	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported

Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone	S	Oral	7.5 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, Q12h	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, Q12h	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Unk	Not Reported
	Apo-Prednisone	S	Oral	Unk	Not Reported
	Cetirizine	S	Unknown	10 Milligram	Not Reported

Chlorhexidine	S	Topical	Unk	Not Reported
Chlorhexidine	S	Unknown	Unk	Not Reported
Chlorhexidine Gluconate	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	S	Unknown	Unk	Not Reported
Periogard	S	Buccal	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	10 Milligram	Not Reported
Cortison	S	Topical	25.0 Milligram	Not Reported
Pseudoephedrine	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	S	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Tylenol W/Codeine	C	Unknown	Unk	Not Reported
Desogestrel & Ethinyl Estradiol	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Cetirizine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17563464	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022239		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb

Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone Acetonide	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Anakinra	S	Unknown	50 Milligram	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	1.5 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	50 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 12 Every 2 Weeks	Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Immune Globulin Iv	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17580328	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA0808		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Kineret			S	Unknown			Not Reported

Administered; Drug Ineffective; No Adverse Event; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Dextromethorphan Hydrobromide	S	Unknown		Not Reported
	Eletriptan Hydrobromide	S			Not Reported
	Eletriptan Hydrobromide	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Mg Once Monthly	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz Xr	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Month	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

Remicade	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Prednisone	S	Unknown		Not Reported
Calcium	C	Oral		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Cipralex	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown	Dose: 0.625 Mg	Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown	Dose: 0.5 Mg	Not Reported
Gabapentin	C	Oral		Not Reported

	Gabapentin	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown	Dose: 12.5 Mg	Not Reported
	Hydromorphone Hcl	C	Oral		Not Reported
	Hydromorphone Hcl	C	Oral		Not Reported
	Mupirocin	C	Topical		Not Reported
	Pantoloc	C	Unknown		Not Reported
	Shark Liver Oil	C	Unknown		Not Reported
	Tapentadol Hydrochloride	C	Unknown		Not Reported
	Taro-Mupirocin	C	Topical		Not Reported
	Tramacet	C	Oral		Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported
	Vitamin D	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17633457	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1653		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Gold	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S		Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Cellcept	S	Unknown	Not Reported
Plaquenil	S		Not Reported
Sulfasalazine	S		Not Reported
Sulfasalazine	S		Not Reported
Celebrex	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Humira	C	Subcutaneous	Not Reported
Celebrex	C	Unknown	Not Reported

	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17718685	EXPEDITED (15-DAY)		DS, OT	CA-COLGATE PALMOLIVE COMPANY-20200400745			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling;	Chlorhexidine Unspecified			S	Unknown			Colgate
	Periogard Alcohol Free Rinse			S	Buccal	Alcohol Free		Colgate
	Chlorhexidine Gluconate Unspecified			S	Oral	Oral Rinse		Colgate
	Oxycodone			S				Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	3011.2 Milligram, 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2912 Milligram, 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, 1 Day		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, 1 Week		Not Reported

Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Cortisone	S	Topical	25 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, 1 Day	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Milligram, 1 Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram, Cyclical	Not Reported
	Remicade	S		Unk	Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Sulfamethoxazole	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, 1 Week	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cetirizine	S	Unknown	10 Milligram	Not Reported
	Prednisone	S	Oral	7.5 Milligram	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, 1 Day	Not Reported
	Cimzia	S	Subcutaneous		Not Reported

Hydroxychloroquine	S	Oral	400 Milligram, 1 Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, 1 Day	Not Reported
Sulfamethoxazole And Trimethoprim	S			Not Reported
Arava	S	Oral	20 Milligram, 24 Hour	Not Reported
Chloraprep	S		Topical	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Leflunomide	S	Oral		Not Reported
Oxycodone Hydrochloride	S			Not Reported
Oxycodone Hydrochloride	S	Unknown	Cr Tablets (Similar To Din #02372525)	Not Reported
Tofacitinib	S	Unknown	10 Milligram, 1 Day	Not Reported
Reactine [Cetirizine Hydrochloride]	C			Not Reported
Salazopyrin	C	Unknown		Not Reported
Pantoprazole Sodium	C			Not Reported
Pantoloc [Pantoprazole]	C			Not Reported
Cetirizine Dihydrochloride	C			Not Reported
Paracetamol/Codeine	C			Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Tylenol With Codeine	C			Not Reported
Tylenol [Paracetamol]	C			Not Reported
Desogestrel And Ethinylestradiol	C			Not Reported
Ibuprofen	C			Not Reported
Zopiclone	C			Not Reported
Marvelon 28	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17732668	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC-2020168162		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycin	S	500 Mg, Daily	Pfizer
	Dexmedetomidine Hydrochloride	S	Unk	Pfizer
	Hydroxychloroquine	S	400 Mg, Daily	Not Reported
	Favipiravir	C	Unk	Not Reported
	Methylprednisolone	C	1 Mg/Kg	Not Reported
	Ceftriaxone	C	2 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17736942	EXPEDITED (15-DAY)		DS	CA-ROCHE-2589878		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis;	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 365.0	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

Topicort (Canada)	S	Cutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Methotrexate Sodium	S	Subcutaneous	Not Reported
Paracetamol	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17982856	EXPEDITED (15-DAY)		OT	CA-ACCORD-188473		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Unknown	Not Specified		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18031442	EXPEDITED (15-DAY)		OT	CA-ACCORD-190570		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18068604	EXPEDITED (15-DAY)		OT	NVSC2020US208811		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Foetal Death; Haemolysis; Hepatic Enzyme Abnormal; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Thrombocytopenia	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18069015	EXPEDITED (15-DAY)		OT	NVSC2020BR206552		44 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular	Hydroxychloroquine			S	Unknown	Unk		Novartis

Insufficiency; Maternal Exposure During Pregnancy; Pao2/Fio2 Ratio Decreased; Premature Delivery; Product Use In Unapproved Indication; Respiratory Disorder; Respiratory Rate Increased	Azithromycin		S	Unknown	Unk	Not Reported
	Ceftriaxone		S	Unknown	Unk	Not Reported
	Oseltamivir		S	Unknown	Unk	Not Reported
	Midazolam		C	Unknown	Unk	Not Reported
	Fentanyl		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18129138	EXPEDITED (15-DAY)		OT	CA-ACCORD-194497		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18131139	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020291169		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Ageusia; Anal Incontinence; Arthropathy; Asthenia; Back Pain; Chest Pain; Chills; Condition Aggravated; Decreased Appetite; Depressed Mood; Diarrhoea; Discomfort; Eructation; Faeces Discoloured; Fatigue; Frequent Bowel Movements; Gait Disturbance; Headache; Malaise; Meniscus Injury; Musculoskeletal Chest Pain; Nausea; Osteoarthritis; Pain; Pain; Patella Fracture; Productive Cough; Pyrexia; Rash; Somnolence; Spinal Pain; Ulcer; Vision Blurred; Weight Abnormal	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Celebrex			C	Oral	200 Mg, 2x/Day		Not Reported
	Premarin			C	Unknown	0.625 Ug		Not Reported
	Rabeprazole			C	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18143561	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1812767		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bk Virus Infection; Coronavirus Infection; Corynebacterium Infection; Enterococcal Infection; Malnutrition; Morganella Infection; Off Label Use; Pleural Effusion; Pneumonia;	Mycophenolate-Mofetil			S	Unknown	2000 Milligram Daily;		Teva
	Mycophenolate-Mofetil			S	Unknown			Teva
	Mycophenolate-Mofetil			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported

Pneumonia Klebsiella; Pulmonary Oedema; Renal Tubular Necrosis; Respiratory Failure; Staphylococcal Bacteraemia; Staphylococcal Infection; Stenotrophomonas Infection; Urinoma	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Teva
	Tacrolimus	S	Unknown	Unknown Initial Dose	Not Reported
	Tacrolimus	S	Unknown	Dose Corresponding To A Trough Goal Of 5-8 Microg/Ml.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18146802	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1812696		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy; Off Label Use	Azithromycin			S	Unknown	Administered For Unknown Days During Pregnancy And Then For 5 Days After Pregnancy		Not Reported
	Hydroxychloroquine			S	Unknown	Administered For Unknown Days During Pregnancy And Then For 3 Days After Pregnancy		Teva
	Tocilizumab			S	Unknown	Two Doses Administered After Fetal Demise		Not Reported
	Ceftriaxone			S	Unknown	Administered For Unknown Days During Pregnancy For Covid-19 Pneumonia (Off Label) And Then For 4 ...		Not Reported
	Ceftriaxone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18165879	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1815202		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Electrocardiogram Qt	Hydroxychloroquine			S	Other			Teva

Prolonged; Hypotension; Off Label Use	Hydroxychloroquine	S		Teva
	Norepinephrine	S	Intravenous (not otherwise specified)	Teva
	Oseltamivir	S	Unknown	Teva
	Oseltamivir	S		Teva
	Propofol	S	Intravenous (not otherwise specified)	Teva
	Cisatracurium	S	Intravenous (not otherwise specified)	Not Reported
	Cefepime	S	Intravenous (not otherwise specified)	Not Reported
	Fentanyl	S	Intravenous (not otherwise specified)	Not Reported
	Midazolam	S	Intravenous (not otherwise specified)	Not Reported
	Vancomycin	S	Intravenous (not otherwise specified)	Not Reported
	Vancomycin	S		Not Reported
	Doxycycline	S	Intravenous (not otherwise specified)	Not Reported
	Doxycycline	S		Not Reported
	Immune Globulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin [Immunoglobulin Human Normal]	S		Not Reported
	Amiodarone	S	Intravenous (not otherwise specified)	Not Reported
	Metformin	C	Unknown	Not Reported
	Insulin Lispro	C	Unknown	Not Reported
	Atenolol	C	Unknown	Not Reported
	Losartan	C	Unknown	Not Reported
	Heparin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18199716	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-26589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution, Single Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18199910	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3484095-00		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatotoxicity; Off Label Use	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax			S	Oral	500 Mg Compresse Rivestite Con Film		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18199939	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS		4 YR	Male	FRA

INC.-2020-05076

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18200272	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-031			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Decreased Appetite; Malaise; Nausea; Night Sweats; Nightmare; Weight Decreased	Methotrexate			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18200666	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-05003		35 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Azithromycin			S	Unknown	500 Milligram		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram		Lupin
	Methylprednisolone			S	Intramuscular	40 Milligram		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Lupin
	Oseltamivir			S	Unknown	75 Milligram		Lupin
	Favipiravir			S	Unknown	200 Milligram		Not Reported
	Piperacillin			S	Intravenous (not otherwise specified)	4.5 Milligram		Not Reported
	Enoxaparin			S	Subcutaneous	0.6 Milligram		Not Reported

	Insulin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18200684	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-197255		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Ventricular Extrasystoles	Hydroxychloroquine			S				Not Reported
	Ondansetron			S				Accord
	Azithromycin			S				Not Reported
	Tacrolimus			C				Not Reported
	Ceftriaxone			C				Not Reported
	Tamiflu			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18200702	EXPEDITED (15-DAY)		HO, OT	QA-AUROBINDO-AUR-APL-2020-040542		26 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypochromic Anaemia; Off Label Use	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Piperacillin+Tazobactam			S				Aurobindo
	Piperacillin+Tazobactam			S				Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Oseltamivir			C	Oral	150 Milligram, Two Times A Day		Not Reported
	Oseltamivir			C				Not Reported
	Oseltamivir			C				Not Reported
	Lopinavir/Ritonavir			C	Oral	Unk, Two Times A Day 400 Mg/100 Mg		Not Reported
	Lopinavir/Ritonavir			C				Not Reported
	Lopinavir/Ritonavir			C				Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Milligram, Daily		Not Reported
	Azithromycin			C				Not Reported
	Azithromycin			C				Not Reported

	Ceftriaxone	C	Unknown	2 Gram, Once A Day	Not Reported
	Ceftriaxone	C			Not Reported
	Ceftriaxone	C			Not Reported
	Methylprednisolone	C	Unknown	40 Milligram, Two Times A Day	Not Reported
	Methylprednisolone	C			Not Reported
	Methylprednisolone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18200720	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05170		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Darunavir And Cobicistat			C	Intracardiac	Unk		Not Reported
	Dupilumab			C	Intracardiac	Unk (Action Taken: Therapy Continued)		Not Reported
	Ceftriaxone			C	Intracardiac	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18200735	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2658055		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Gastric Disorder; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Actemra	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apremilast	S	Oral	Not Reported
	Apremilast	S		Not Reported
	Apremilast	S		Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Ibuprofen	S	Oral	Not Reported
Infliximab	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Motrin Ib	S	Oral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported

Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Otezla	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Stelara	S		Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Uloric	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Nitrazepam	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported
Febuxostat	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Colchicine	C	Unknown	Not Reported
Cyclosporin A	C	Unknown	Not Reported
Dexilant	C	Oral	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18200911	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202008008184			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Haemorrhage; Retinal Vein Occlusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201592	EXPEDITED (15-DAY)		HO, LT, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-05098		28 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Electrocardiogram Qt Prolonged; Off Label Use; Product Communication Issue	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	1600 Milligram (Overdose)		Lupin
	Oseltamivir			S	Unknown	75 Milligram, Bid		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201603	EXPEDITED (15-DAY)		OT	CA-ACCORD-197145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Sulfasalazine		C	Unknown	Not Reported
	Wellbutrin		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201969	EXPEDITED (15-DAY)		OT	CA-ACCORD-197321			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201970	EXPEDITED (15-DAY)		OT	CA-ACCORD-197151			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate			S	Oral	Frequency: 1 Every 1 Weeks		Not Reported
	Arava			S				Not Reported
	Enbrel			S		Frequency: 1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S		Frequency: 1 Every 1 Days		Not Reported
	Myochrysine			S	Intramuscular	Frequency: 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Methotrexate			S	Oral	Frequency: 1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201973	EXPEDITED (15-DAY)		OT	CA-ACCORD-197333		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Codeine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201975	EXPEDITED (15-DAY)		OT	CA-ACCORD-197285		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Methotrexate		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201980	EXPEDITED (15-DAY)		OT	CA-ACCORD-197360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	2 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201981	EXPEDITED (15-DAY)		OT	CA-ACCORD-197367			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Not Reported
	Hydroxychloroquine	S	Oral	Frequency: Every 1 Days	Not Reported
	Leflunomide	S			Not Reported
	Sulfasalazine	S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Depo-Medrol	C	Intra-articular	Dosage Form: Suspension Intra-Articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201985	EXPEDITED (15-DAY)		OT	CA-ACCORD-197275		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Accord
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201988	EXPEDITED (15-DAY)		OT	CA-ACCORD-197336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance;	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Gastrointestinal Disorder; Hepatitis; Rash	Sulfasalazine		S	Unknown	1 Every 1 Days	Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201992	EXPEDITED (15-DAY)		OT	CA-ACCORD-197324			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202232	EXPEDITED (15-DAY)		OT	DE-TEVA-2020-DE-1819678		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Hydroxychloroquine			S	Transplacental	400 [Mg / D (200-0-200)] 2 Separated Doses		Teva
	L-Thyroxin			C	Transplacental	25 [Ug/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202249	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1634		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis; Tuberculosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Folic Acid	C	Unknown	Not Reported
Medrol	C	Unknown	Not Reported
Calcium & Vitamin D	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202253	EXPEDITED (15-DAY)		OT	DE-TEVA-2020-DE-1819690		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	7.5 Mg		Actavis
	Hydroxychloroquine			S	Transplacental	300 [Mg / D] / Alternating: 200 And 400mg Daily		Teva
	Rhophylac			C	Transplacental			Not Reported
	Infliximab			C	Transplacental	Last Exposure Two Weeks Before Conception		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202311	EXPEDITED (15-DAY)		OT	CA-ACCORD-197278		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Methotrexate			S	Unknown			Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202312	EXPEDITED (15-DAY)		HO	CA-ACCORD-197277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Methotrexate			S	Unknown	Not Specified		Accord
	Paracetamol			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Morphine			S	Unknown	Not Specified		Not Reported
	Prednisone			S	Unknown	1 Every 1 Days, Not Specified		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202326	EXPEDITED (15-DAY)		OT	CA-ACCORD-197155			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown	Not Specified		Accord
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Not Specified	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Powder For Suspension Subcutaneous	Not Reported
	Xeljanz	C	Oral	2 Every 1 Days	Not Reported
	Cortisone	C	Subcutaneous		Not Reported
	Desoximetasone	C	Oral	Not Specified	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Xeljanz	C	Oral	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202491	EXPEDITED (15-DAY)		OT	CA-ACCORD-197106		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Parenteral	1 Every 1 Weeks		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	Subcutaneous Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	C	Unknown		Not Reported
	Azathioprine	C	Unknown	1 Every 1 Days	Not Reported
	Ciclosporin	C	Unknown	1 Every 1 Days	Not Reported
	Minocycline	C	Unknown	1 Every 1 Days	Not Reported
	Penicillamine	C	Unknown		Not Reported
	Prednisone	C	Unknown	2 Every 1 Days	Not Reported
	Methotrexate	S	Oral	1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202493	EXPEDITED (15-DAY)		OT	CA-ACCORD-197107		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown	1 Every 1 Weeks		Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202494	EXPEDITED (15-DAY)		OT	CA-ACCORD-197304			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202497	EXPEDITED (15-DAY)		OT	CA-ACCORD-197327			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Accord
	Vioxx			S				Not Reported
	Rituximab			S				Not Reported
	Orencia			S				Not Reported
	Naprosyn			S		2 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral	1 Every 24 Hours		Not Reported
	Anakinra			S				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202498	EXPEDITED (15-DAY)		OT	CA-ACCORD-197330		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective;	Methotrexate			S	Unknown			Not Reported

Gait Disturbance; Nerve Compression	Hydroxychloroquine		S	Unknown	1 Every 1 Days	Not Reported
	Actemra		S	Unknown		Not Reported
	Orencia		S	Unknown	1 Every 1 Weeks	Not Reported
	Sulfasalazine		S	Unknown	1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202738	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1073986		74 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Haematocrit Decreased; Off Label Use; Platelet Count Decreased; Purpura; Soft Tissue Infection	Lopinavir/Ritonavir			S	Unknown	Unk Unk, Bid200/50mg Two Tablets		Mylan
	Enoxaparin			S	Unknown	6000 International Unit		Mylan
	Ruxolitinib			S	Unknown	5 Milligram2 Tablets/Day For 2 Days, And 4 Tablets For 3 Days		Mylan
	Dexamethasone			S	Unknown	20 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Mylan
	Tocilizumab			S	Subcutaneous	162 Milligram, Qw 2 Injections Per 2 Cycles A Week		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203155	EXPEDITED (15-DAY)		OT	CA-ACCORD-197090		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Naproxen			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Month		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous, 1 Every 1 Month	Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203158	EXPEDITED (15-DAY)		OT	CA-ACCORD-197148		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Oral	1 Every 12 Hours		Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Xeljanz			S	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203169	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025610			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown	500.0 Mg		Not Reported
Desoximetasone	C	Unknown	10.0 Mg, 1 Every 24 Hours		Not Reported
Diclofenac	C	Unknown	100.0 Mg, 1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203178	EXPEDITED (15-DAY)		DE	CA-CELLTRION INC.-2020CA026018			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma; Off Label Use	Rituximab (Unknown)			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Every 1 Day		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown	15 Mg, Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203201	EXPEDITED (15-DAY)		HO, OT	TR-AMNEAL PHARMACEUTICALS-2020-AMRX-02564		28 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Asthenia; Diarrhoea; Electrocardiogram Qt Prolonged; Nausea; Off Label Use; Sinus Bradycardia	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2 /Day For 5 Days		Amneal
	Hydroxychloroquine Sulfate			S	Oral	1600 Milligram, Accidentally Taken		Amneal

	Oseltamivir	C	Oral	75 Milligram, 2 /Day For 5 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203413	EXPEDITED (15-DAY)		HO	FR-MYE-2020M1045644AA		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Paracetamol			S	Oral	4 Gram, Qd		Mylan
	Anastrozole			S	Oral	1 Milligram, Qd		Not Reported
	Augmentin /00756801/			S	Intravenous (not otherwise specified)	3 Gram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan
	Amlor			S	Oral	1 Dosage Form, Qd		Mylan
	Colchimax /01722001/			S	Oral	1 Dosage Form, Qd		Mylan
	Nefopam			S	Oral	80 Milligram, Qd		Mylan
	Arimidex			S	Oral	1 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203569	EXPEDITED (15-DAY)		OT	NVSC2020DE234696			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Progression; Metastases To Liver; Pancreatic Carcinoma Metastatic; Product Use In Unapproved Indication	Mekinist			S	Unknown			Novartis
	Gen-Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18203581	EXPEDITED (15-DAY)		OT	NVSC2020US234841		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Hypoxia; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate Tablets Usp		S	Unknown	Unk	Novartis
	Methylprednisolone		S	Unknown	Unk	Not Reported
	Tocilizumab		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18204058	EXPEDITED (15-DAY)		OT	BR-UCBSA-2019030382		56 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Gait Inability; Headache; Heart Rate Increased; Heat Exhaustion; Pain; Product Dose Omission; Rheumatoid Arthritis	Certolizumab Pegol Ra			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Ucb
	Hydroxychloroquine			S		Unk		Not Reported
	Betamethasone Dipropionate			C	Intramuscular	Unk		Not Reported
	Hydrochlorothiazide			C	Oral	Unk		Not Reported
	Captopril			C	Oral	Unk		Not Reported
	Eritromicina [Erythromycin]			C	Oral	Unk		Not Reported
	Decadron [Dexamethasone]			C				Not Reported
	Tramal			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Profenid			C		Unk		Not Reported
	Dipyrone			C				Not Reported
	Prednisona			C	Oral	Unk		Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18204169	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-067607			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18204831	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200820180			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective; Drug Intolerance; Fatigue	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Pantoloc /01263201/			S	Unknown			Not Reported
	Voltaren /00372301/			S	Unknown			Not Reported

	Acetaminophen			C	Unknown					Not Reported
	Celebrex			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18204999	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025630			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Rash; Upper Respiratory Tract Infection	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Week		Not Reported
	Actemra			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205024	EXPEDITED (15-DAY)		LT, OT	CA-CELLTRION INC.-2020CA026114			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Rituximab (Unknown)			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205188	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025586			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	8 Mg/Kg, 1 Every 1 Months	Not Reported
	Apo-Prednisone	S	Oral	50 Mg	Not Reported
	Apo-Prednisone	S			Not Reported
	Apo-Prednisone	S	Oral	30 Mg, 1 Every 1 Days	Not Reported
	Apo-Prednisone	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Oral	15 Mg, 1 Every 1 Weeks	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Citalopram Hydrobromide	C	Unknown		Not Reported
	Ketoprofen	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Omeprazole	C	Unknown		Not Reported
	Prednisone	C	Oral	5 Mg	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205213	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025620			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1 Every 1 Day		Not Reported
	Enbrel			S	Unknown	25 Mg, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	20 Mg, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205232	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025545			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab (Unknown)			S	Unknown			Not Reported
	Doxycycline			S	Unknown	50 Mg		Not Reported
	Doxycycline Hyclate			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1 Every 1 Days		Not Reported

Orencia	S	Unknown			Not Reported
Simponi	S	Subcutaneous	50 Mg, 1 Every 1 Months		Not Reported
Methotrexate	C	Unknown	25 Mg		Not Reported
Prednisone	C	Unknown	10 Mg, 1 Every 1 Days		Not Reported
Xeljanz	C	Unknown	50 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205264	EXPEDITED (15-DAY)		OT	NVSC2020US237107			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Ventricular Tachycardia	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	600 Mg, Bid		Novartis
	Propofol			C	Intravenous drip	Continous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205343	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Physical Health Deterioration; Mobility Decreased; Musculoskeletal Pain; Nervousness; Pain; Pain In Extremity	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Diclofenac Sodium			S	Oral			Actavis
	Prednisone			S	Unknown			Actavis
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205460	EXPEDITED (15-DAY)		OT	TR-FRESENIUS KABI-FK202008705			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Ventricular Tachycardia	Azithromycin (Manufacturer Unknown)		S	Unknown	Unknown	Fresenius Medical Care
	Hydroxychloroquine		S	Unknown	Unknown	Not Reported
	Favipiravir		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18205462	EXPEDITED (15-DAY)		OT	TR-FRESENIUS KABI-FK202008706			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Azithromycin (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Favipiravir			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18206106	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-067652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Intramuscular	80 Milligram, Qd		Not Reported

Papular; Rash Pruritic;
Rheumatoid Lung;
Synovial Cyst; Synovitis;
Tenosynovitis; Viral Upper
Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18206577	DIRECT	N	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	15624086	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557445-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

	Mycophenolate Mofetil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	16177041	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190403869		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Tylenol			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	17390099	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200153298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Stelara	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cosentyx	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Otezla	S	Oral	Not Reported
Otezla	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	17567096	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318557		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	17605666	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332776		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Otezla	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sirukumab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	C	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	17880965	EXPEDITED (15-DAY)		OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048086			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Alkaline Phosphatase Abnormal; Decreased Appetite; Fatigue; Gamma-Glutamyltransferase Increased; Malaise; Nausea; Product Administration Interrupted; Therapy Interrupted; Weight Decreased; White Blood Cell Count Decreased	Ursodeoxycholic Acid			S	Unknown	750 Milligram, Od		Glenmark
	Ursodeoxycholic Acid			S	Unknown	750 Milligram, Od		Glenmark
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Ocaliva			S	Oral	5 Milligram, Od		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18092228	EXPEDITED (15-DAY)		OT	CA-ACCORD-193344			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Oral			Accord
	Vioxx			S				Not Reported
	Rituximab			S				Not Reported
	Orencia			S				Not Reported
	Naprosyn			S	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Arava			S	Oral	1 Every 24 Hours		Not Reported
	Anakinra			S				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18120183	EXPEDITED (15-DAY)		DS, HO, OT	AU-JNJFOC-20200745075			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal	Topiramate			S	Oral			Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported
	Colecalciferol			S	Unknown			Not Reported
	Ezetimibe			S	Unknown			Not Reported
	Glyceryl Trinitrate			S	Oral			Not Reported
	Ivabradine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Mycophenolate Mofetil	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Prasugrel	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Reboxetine	S	Unknown	Not Reported
	Sildenafil	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Endone	S	Oral	Not Reported
	Glucagen /00157801/	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Mirena	S	Unknown	Not Reported
	Novorapid	S	Unknown	Not Reported
	Oxycontin	S	Oral	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	5-Methyltetrahydrofolate W/Cyanocobalamin/Fol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18122098	EXPEDITED (15-DAY)		DE, OT	DE-AUROBINDO-AUR-APL-2020-038108		71 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Respiratory Failure	Aciclovir			S	Unknown	Unk		Aurobindo
	Caspofungin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Piperacillin			S	Unknown	Unk		Not Reported
	Tazobactam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18126759	EXPEDITED (15-DAY)		DE, OT	DE-AUROBINDO-AUR-APL-2020-038109		76 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiopulmonary Failure; Drug Ineffective; Off Label Use	Aciclovir			S	Unknown	Unk		Aurobindo
	Caspofungin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Maraviroc			S	Unknown	Unk		Not Reported
	Piperacillin			S	Unknown	Unk		Not Reported
	Tazobactam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18147498	EXPEDITED (15-DAY)		DE, OT	DE-AUROBINDO-AUR-APL-2020-039529		72 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Respiratory Failure	Aciclovir			S	Unknown	Unk		Aurobindo
	Caspofungin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Maraviroc			S	Unknown	Unk		Not Reported
	Piperacillin			S	Unknown	Unk		Not Reported
	Tazobactam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18153829	EXPEDITED (15-DAY)		LT, OT	NVSC2020US226171		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis Crisis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oropharingeal	400 Mg, Bid (On Day 2)		Novartis
	Hydroxychloroquine			S	Oropharingeal	200 Mg, Tid (From 3-8)		Novartis
	Hydroxychloroquine			S	Oropharingeal	200 Mg, Bid (On Day 12-		Novartis

			17)	
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Once/Single (On Day 1)	Not Reported
Azithromycin	S	Oropharingeal	250 Mg, Qd (From Day 2-5)	Not Reported
Azithromycin	S	Oropharingeal	250 Mg, Qd (On Day 11)	Not Reported
Lovenox	C	Unknown	Unk	Not Reported
Colace	C	Unknown	Unk	Not Reported
Precedex	C	Intravenous drip	Unk	Not Reported
Protonix "Pharmacia"	C	Unknown	Unk	Not Reported
Versed	C	Intravenous drip	Unk	Not Reported
Senna	C	Unknown	Unk	Not Reported
Propofol	C	Intravenous drip	Unk	Not Reported
Lasix	C	Intravenous (not otherwise specified)	60 Mg	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	1q Q12h	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
Heparin	C	Intravenous drip	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
Insulin Glargine	C	Unknown	Unk	Not Reported
Fentanyl	C	Intravenous drip	Unk	Not Reported
Regelan	C	Intravenous (not otherwise specified)	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18160899	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP018021		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Prednisone	S	Oral	5 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Apotex
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Apotex
	Leflunomide	S	Oral	10 Milligram	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	20 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	20 Milligram, Qd	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18180374	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016163			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	15 Milligram, Q.Wk.		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q.O.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	400.0 Milligram		Not Reported
Methylprednisolone	S	Unknown	80 Milligram		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	400 Milligram (1 Every 8 Weeks)		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Rituxan	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown			Not Reported
Naproxen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204183	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Rituximab (Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Weeks		Not Reported
	Actemra			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204311	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA025559			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Rituximab (Unknown)	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram	Not Reported
	Plaquenil Sulfate	S	Unknown	400 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	C	Subcutaneous	162 Milligram, 1 Every 1 Weeks	Not Reported
	Advil /00044201/	C	Unknown		Not Reported
	Arava	C	Unknown	20 Milligram, 1 Every 1 Weeks	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	200 Milligram, 1 Every 1 Days	Not Reported
	Ketorolac	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204571	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05123		47 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin

Arbidol	C	Oral	0.2 Gram, Tid		Not Reported
Lopinavir/Ritonavir	C	Oral	500 Milligram, Bid		Not Reported
Interferon Alfa	C		500 International Unit, Bid		Not Reported
Thymalfasin	C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patients' Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204654	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05124		87 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gait Disturbance; Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patients' Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204666	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05125		17 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week		Not Reported

					According To Patients' Response				

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204688	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05126		63 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patients' Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204750	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05182		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Oral	200 Milligram		Lupin
	Azithromycin			S	Oral	500 Milligram		Lupin
	Acetaminophen			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	10 Milligram		Not Reported
	Pantoprazole			C	Unknown	40 Milligram		Not Reported
	Rivaroxaban			C	Unknown	20 Milligram		Not Reported
	Omega-3 Fatty Acids			C	Unknown	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18204919	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		75 YR	Female	FRA

2020RR-259510

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Paracetamol		Y	S	Oral	4 Gram, Daily		Ohm Lab
	Arimidex 1 Mg, Comprime Pellicule			S	Oral	1 Milligram, Daily		Not Reported
	Amlor 10 Mg, Gelule			S	Oral	1 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	400 Milligram, Daily		Not Reported
	Colchimax, Comprime Pellicule			S	Oral	1 Dosage Form, Daily		Not Reported
	Augmentin			S	Intravenous (not otherwise specified)	3 Gram, Daily		Not Reported
	Nefopam (Chlorhydrate De)			S	Oral	80 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18205002	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818540			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18205055	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818392		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Subcutaneous			Barr
	Prednisone	S	Unknown			Actavis
	Arava	S	Unknown			Not Reported
	Celebrex	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported
	Simponi	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18205400	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025622			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	C	Unknown	500.0 Milligram, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18205449	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206012	EXPEDITED (15-DAY)		HO, OT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-055072			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Syncope	Azithromycin			S	Oral	500 Milligram, Single		Zydus Pharm
	Azithromycin			S	Oral	250 Milligram, Qd		Zydus Pharm
	Sotalol			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206042	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-197290		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Sleep Disorder; Spinal Stenosis	Methotrexate			S				Accord
	Plaquenil			S				Not Reported
	Orencia			S				Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol / Acetaminophen			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S		1 Every 1 Days		Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Arava			S				Not Reported
	Risedronic Acid			C				Not Reported
	Premarin			C				Not Reported
	Vagifem			C				Not Reported
	Nortriptyline			C				Not Reported
	Nortriptyline			C				Not Reported
	Metformin			C				Not Reported
	Lyrica			C				Not Reported
	Lorazepam			C				Not Reported

	Ergocalciferol	C			Not Reported
	Calcium Carbonate	C			Not Reported
	Paracetamol	C			Not Reported
	Plaquenil	S	1 Every 1 Days		Not Reported
	Methotrexate	S			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206047	EXPEDITED (15-DAY)		OT	CA-ACCORD-197092		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Methotrexate			S	Subcutaneous	1 Every 1 Weeks, Not Specified		Accord
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days, Not Specified		Not Reported
	Naprosyn			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	1 Every 4 Months, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	1 Every 1 Days		Not Reported
	Naprosyn			S	Unknown	2 Every 1 Days		Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	1 Every 4 Week, Solution Subcutaneous		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported

	Methotrexate		S	Subcutaneous	1 Every 1 Weeks, Not Specified	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206591	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025629			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206596	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025591			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Bifidobacterium Bifidum			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Align			C	Unknown			Not Reported

Celebrex	C	Unknown			Not Reported
Loperamide	C	Oral	2.0 Milligram		Not Reported
Methotrexate	C	Unknown			Not Reported
Pantoprazole	C	Unknown			Not Reported
Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206601	EXPEDITED (15-DAY)			CA-CELLTRION INC.-2020CA025592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500.0 Milligram, 1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206612	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025625			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Treatment	Rituximab (Unknown)			S	Intravenous (not			Not Reported

Failure			otherwise specified)		
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Procytox	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206736	EXPEDITED (15-DAY)		OT	SE-ACCORD-197729			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Ocular Icterus; Pruritus; Yellow Skin	Hydroxychloroquine			S				Not Reported
	Zink			S		120 Mg Per Day		Not Reported
	Azithromycin			S		500 Mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18206850	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2020M1074057		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Hydroxychloroquine			S	Unknown			Mylan
	Azithromycin			S	Unknown			Mylan
	Furosemide			S	Unknown			Mylan
	Meropenem			S	Unknown			Mylan
	Piperacillin/Tazobactam			S	Unknown			Mylan
	Unfractionated Heparin			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207020	EXPEDITED (15-DAY)		OT	NVSC2020US237111			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Thrombocytopenia	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	600 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207045	EXPEDITED (15-DAY)		LT, OT	CA-JNJFOC-20200834879		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207178	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200834221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207183	EXPEDITED (15-DAY)		DS	CA-JNJFOC-20200834171		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site	Simponi			S	Subcutaneous			Not Reported

Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Allopurinol		C	Unknown	Not Reported
	Hydromorph Contin		C	Unknown	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207185	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200834193			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207203	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818369		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported

	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207254	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818390			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207256	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]					
	Rituximab	S	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
	Simponi	C	Subcutaneous			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207257	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1818389		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207495	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818529		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Arava	S	Unknown			Not Reported
Desoximetasone	S	Oral			Not Reported
Desoximetasone	S	Unknown			Not Reported
Enbrel	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Plaquenil	S	Unknown			Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207497	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline Hyclate			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207498	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818578			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Leukopenia	Codeine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207499	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1818526			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207529	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818636		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207960	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1074274		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Clobetasol			S	Topical	Unk		Mylan
	Prednisone			S	Unknown	Received Multiple Prednisone Courses, With Doses Up To 120mg Tapered Over 3 Months		Mylan
	Prednisone			S	Unknown	20 Milligram		Mylan

	Hydroxychloroquine		S	Unknown	Unk	Mylan
	Hydroxychloroquine		S	Unknown	600 Milligram, Qd	Mylan
	Dapsone		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208271	EXPEDITED (15-DAY)		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05130		72 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobinuria; Haemolytic Anaemia; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lopinavir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208514	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA202008006918		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Cymbalta			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unknown		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208774	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05132		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Doxycycline			S	Oral	200 Milligram		Lupin
	Doxycycline			S				Lupin
	Hydroxychloroquine			S	Oral	400 Milligram		Lupin

Misoprostol	S	Vaginal	400 Microgram		Novel Labs
Flagyl [Metronidazole]	C	Unknown	Unk		Not Reported
Vancomycin	C	Unknown	Unk		Not Reported
Aztreonam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208852	EXPEDITED (15-DAY)		HO	FR-FRESENIUS KABI-FK202008699		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Linezolid (Manufacturer Unknown)			S	Intravenous drip	Unspecified		Fresenius Medical Care
	Imipenem/Cilastatin Sodium			S	Intravenous drip	Unspecified		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unspecified		Not Reported
	Piperacillin Sodium/Tazobactam Sodium			S	Intravenous drip	Unspecified		Not Reported
	Azithromycin			S	Oral	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208923	EXPEDITED (15-DAY)		OT	IT-SA-2020SA227697			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Off Label Use; Prothrombin Time Prolonged	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Dexamethasone Salt Not Specified			S		8 Mg, Bid		Not Reported
	Rifampicin			S		Unk		Sanofi
	Ethambutol			S		Unk		Not Reported
	Oxygen			C		15 L, Qmn		Not Reported
	Enoxaparin			C		4000 Iu		Not Reported
	Lopinavir/Ritonavir			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18209059	EXPEDITED (15-DAY)		OT	NVSC2020ES236842		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Chorioretinitis; Macular Degeneration	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg (12 Hours)		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18209181	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818666			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18209222	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-066400		56 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram T Wave Inversion; Off Label Use	Reyataz			S	Oral	400 Milligram, Daily		Bristol Myers Squibb
	Hydroxychloroquine			S	Oral	200 Milligram, 2 Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	16084291	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022664		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Knee Arthroplasty; Live Birth; Maternal Exposure During	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral	2 Gram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Pregnancy; Pain; Pain; Pemphigus; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Systemic Lupus Erythematosus; Wound	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Subcutaneous		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Apo-Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil/00072603/	S	Oral		Not Reported

Plaquenil/00072603/	S			Not Reported
Reactine//Cetirizine Hydrochloride	S	Unknown		Not Reported
Reactine//Cetirizine Hydrochloride	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral	500 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Sarilumab	S	Unknown		Not Reported
Sarilumab	S			Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Topical		Not Reported
Topicort	S	Subcutaneous		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram Daily;	Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	16886720	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2946845-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Ill-Defined Disorder;	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Sulfathalidine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported

Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Maternal Exposure During Pregnancy; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Weight Increased; Wound	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown	Powder For Infusion	Not Reported
	Cetirizine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexaat	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Arava	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
	Topicort	S	Cutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Ophthalmic		Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported

	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Periogard	S	Unknown	Not Reported
	Atasol [Paracetamol]	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18086068	EXPEDITED (15-DAY)		OT	CA-ACCORD-192698		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Accord
	Methotrexate			S				Accord
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Depo-Provera			S				Not Reported
	Etanercept			S				Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S				Not Reported
	Leflunomide			S				Not Reported
	Medroxyprogesterone			S	Unknown			Not Reported
	Naprosyn			S				Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate			S				Not Reported
	Prednisone			S				Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported

	Anakinra	C			Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Depo-Provera	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18200722	EXPEDITED (15-DAY)		OT	CA-ACCORD-197154		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown	Not Specified		Accord
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Cimzia			C	Unknown	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210042	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818372		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling;	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Stress	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	1 Every 2 Weeks	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Dequalinium Chloride	C			Not Reported
	Mefenamic Acid	C			Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Oral	6 Milligram Daily;	Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210047	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818434			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210079	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1818440		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210132	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-045274		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Off Label Use; Tachyarrhythmia; Tachycardia; Vomiting; Weight Decreased	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210142	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818656			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818537		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium Carbonate/Vitamin D3			C	Unknown			Not Reported
	Hydrocortisone			C				Not Reported
	Pantoloc[Pantoprazole]			C				Not Reported
	Prednisone			C		20 Milligram Daily;		Not Reported
	Tylenol Arthritis Pain 8h			C		4 Dosage Forms Daily;		Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210644	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818671		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

	Enbrel			S	Unknown					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported
	Rituximab			S	Intravenous drip					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210675	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818381		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Doxycycline			S	Unknown			Actavis
	Doxycycline			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown	23 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	24 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	25 Milligram Daily;		Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210718	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818971			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210719	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1818980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness;	Leflunomide			S	Unknown			Barr
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Diclofenac			C				Not Reported

Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methylprednisolone Acetate	C	Intramuscular	80 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210729	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1819071		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Joint Swelling; Malaise; Musculoskeletal Stiffness; Nausea; Pain; Spinal X-Ray Abnormal; Stress; Swelling; Tender Joint Count; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2020	14545702	EXPEDITED (15-DAY)		OT	CA-ROCHE-1715783		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Blood Pressure Diastolic Increased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation;	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015, Most Recent Dose On 06/Jun/2017 (683 Mg)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015		Not Reported

Blood Pressure Increased; Blood Pressure Increased; Blood Pressure Increased; Cough; Decreased Appetite; Epistaxis; Headache; Heart Rate Increased; Influenza Like Illness; Infusion Related Reaction; Infusion Site Pain; Medication Error; Nausea; Pain; Platelet Count Decreased; Pruritus; Pyrexia; Sensation Of Foreign Body; Vomiting; Weight Increased; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Methotrexate	C		Not Reported
	Folic Acid	C		Not Reported
	Atovaquone	C		Not Reported
	Alendronate	C		Not Reported
	Vit D3	C		Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Vitamin C	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2020	18210834	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050675			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Azithromycin		S	Oral	500 Mg Dia	Zydus Pharm
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Dolquine		S	Oral	400 Mg Dia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2020	18210835	EXPEDITED (15-DAY)		OT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050008			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	13059040	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015749		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Apo-Leflunomide			S	Unknown	20 Milligram		Apotex
	Apo-Leflunomide			S	Oral	10 Milligram		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Methotrexate			S	Oral	15 Milligram, Q.Wk.		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Mg, Unk		Not Reported

Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Arava	S	Unknown	10 Mg, Unk		Not Reported
Arava	S	Unknown	20 Mg, Unk		Not Reported
Celebrex	S	Unknown	50 Mg, Q.Wk.		Not Reported
Celebrex	S				Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
Enbrel	S	Unknown	50 Mg, Unk		Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk		Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Unk		Not Reported
Methotrexate	S	Subcutaneous	2.5 Mg, Unk		Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Unk		Not Reported
Orencia	S	Subcutaneous	250 Mg, Unk		Not Reported
Plaquenil /00072602/	S	Unknown	300 Mg, Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Folic Acid	C	Unknown	10 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	14089188	EXPEDITED (15-DAY)		OT	US-BEH-2017084319		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Human Immunoglobulin Iv (Inn)			S	Intravenous (not otherwise specified)	400 1g/Kg		Csl Behring
	Human Immunoglobulin Iv (Inn)			S				Csl Behring
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (At 6 Weeks Gestation)		Not Reported
	Dexamethasone			S	Unknown	8 Mg, Unk		Not Reported
	Dexamethasone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	14089247	EXPEDITED (15-DAY)		OT	US-BEH-2017084346			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Block Congenital	Human Immunoglobulin Iv (Inn)			S	Intra-uterine	Unk		Csl Behring
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (From 6 Weeks Gestation)		Not Reported
	Dexamethasone			S	Unknown	8 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	15682732	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2018CA168554		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adjustment Disorder With Depressed Mood; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Fibromyalgia; Gait Disturbance; General Physical Health	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Zyrtec-D			S	Unknown	10 Mg, Unk		Not Reported
	Phthalylsulfathiazole			S	Subcutaneous	Unk		Not Reported
	Topicort			S	Cutaneous	Unk		Not Reported
	Cirrus			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	20 Mg		Not Reported

Deterioration; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infection; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Range Of Motion Decreased; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Memory Impairment; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Pericarditis; Prescribed Overdose; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Factor Positive; Sleep Disorder; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Vomiting; Walking Aid User; Weight Decreased; Wheezing; Wound; Wound Infection	Cimzia	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine	S	Oral	25 Mg	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
	Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
	Apo-Prednisone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Subcutaneous	Dosage Form: Unspecified	Not Reported
	Humira	S	Subcutaneous	40 Mg, 0.8ml	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Sulfathalidine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfathalidine	S	Oral	500 Mg, Unk	Not Reported
	Tofacitinib	S	Unknown	5 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg, 2x/Day (Bid)	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported

	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Mg	Not Reported
	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Prinivil	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17168352	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019228928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Liver Injury; Off Label Use; Pain; Pemphigus; Product Use Issue; Psoriatic	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Pseudoephedrine Hcl			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

Arthropathy; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Mg	Not Reported

Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
Apo-Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Glaxosmithkline
Quetiapine	C	Unknown	Unk	Glaxosmithkline
Ramipril	C	Unknown	Unk	Glaxosmithkline
Pantoprazole	C	Unknown	Unk	Glaxosmithkline
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17557563	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17605641	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200333272		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Laboratory Test Abnormal; Musculoskeletal Disorder;	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported

Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Asacol	S	Unknown	Not Reported
	Azathioprine	S	Oral	Not Reported
	Budesonide	S		Not Reported
	Entyvio	S	Intravenous (not otherwise specified)	Not Reported
	Vedolizumab	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported

	Lyrica	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Tocilizumab	C	Endocervical	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Wellbutrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17688879	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200421346		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Uveitis	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Sarilumab			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17694005	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419292		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17714374	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428608		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthralgia; Arthropathy; Cervical Vertebral Fracture; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Drug Intolerance; Foot Deformity; Grip Strength Decreased; Hypophagia; Ill-Defined Disorder; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness;	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Malaise; Mobility Decreased; Nausea; Off Label Use; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Gold		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17982166	EXPEDITED (15-DAY)		DS	CA-ACCORD-188308		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Levothyroxine/Levothyroxine Sodium			C				Not Reported
	Folic Acid			C				Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			C				Not Reported
	Bupropion/Bupropion Hydrochloride			C				Not Reported
	Methotrexate			S				Accord
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17982799	EXPEDITED (15-DAY)		HO	CA-ACCORD-188372		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate	S				Accord
	Xeljanz	S	Oral	2 Every 1 Days		Not Reported
	Prednisone	S				Not Reported
	Orencia	S				Not Reported
	Naproxen	S				Not Reported
	Hydroxychloroquine	S				Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel	S				Not Reported
	Actemra	S				Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Folic Acid	C	Subcutaneous			Not Reported
	Hydroxychloroquine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18017063	EXPEDITED (15-DAY)		OT	IT-ROCHE-2636201			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Intentional Product Use Issue; Neutropenia; Off Label Use; Pneumonia; Rash Maculo-Papular; Sepsis; Urinary Tract Infection	Tocilizumab			S	Intravenous (not otherwise specified)	Maximum 800mg, If Required Dose Was Repeated After 24 Hours		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S	Subcutaneous	If Required Dose Was Repeated After 24 Hours		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral	Unless Glucose-6-Phosphate Dehydrogenase Deficient.		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Darunavir			S	Unknown	800 Unit Not Reported		Not Reported

	Ritonavir	S	Unknown	100 Unit Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18030363	EXPEDITED (15-DAY)		OT	CA-ACCORD-189584		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Subcutaneous			Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S		1 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Actonel			S		1 Every 1 Weeks		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Risedronic Acid			S		1 Every 1 Weeks		Not Reported
	Methotrexate			S				Accord
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported

	Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
	Actonel	S		1 Every 1 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Oral		Not Reported
	Apo-Leflunomide	S		1 Every 24 Hours	Not Reported
	Apo-Leflunomide	S	Oral	1 Every 24 Hours	Not Reported
	Apo-Leflunomide	S	Oral	1 Every 1 Hours	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S		4 Every 1 Days	Not Reported
	Hydroxychloroquine	S		2 Every 1 Days	Not Reported
	Hydroxychloroquine	S		1 Every 1 Hours	Not Reported
	Hydroxychloroquine	S		1 Every 1 Weeks	Not Reported
	Risedronic Acid	S	Oral	1 Every 1 Weeks	Not Reported
	Risedronic Acid	S		1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18084591	EXPEDITED (15-DAY)		LT, OT	CA-ACCORD-192823		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dysphonia; Dyspnoea; Odynophagia; Rheumatoid Arthritis; Stridor	Methotrexate			S				Accord
	Golimumab			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18084622	EXPEDITED (15-DAY)		CA	NVSC2020CN211066			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Heart Block Congenital	Hydroxychloroquine		S	Transplacental	Maternal Dose: 400 Mg, Qd	Novartis
	Dexamethasone		S	Transplacental	Maternal Dose: 3 To 7.5 Mg, Qd	Not Reported
	Dexamethasone		S	Transplacental	Maternal Dose: 3.75 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18085171	EXPEDITED (15-DAY)		CA	NVSC2020CN211067			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Block Congenital	Hydroxychloroquine			S	Transplacental	Maternal Dose: 400 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 400 Mg, Qd		Novartis
	Dexamethasone			S	Transplacental	Maternal Dose: 3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18097391	EXPEDITED (15-DAY)		OT	NVSC2020CN212573			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Neonatal Pneumonia; Premature Baby	Hydroxychloroquine Sulfate			S	Transplacental	Maternal Dose: Unk		Novartis
	Methylprednisolone			S	Transplacental	Maternal Dose: Unk		Not Reported
	Oseltamivir			S	Transplacental	Maternal Dose: Unk		Not Reported
	Ribavirin			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18097410	EXPEDITED (15-DAY)		OT	NVSC2020CN212575			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth	Hydroxychloroquine Sulfate			S	Transplacental	Maternal Dose: Unk		Novartis

Weight Baby; Neonatal Pneumonia; Premature Baby	Oseltamivir		S	Transplacental	Maternal Dose: Unk	Not Reported
	Ribavirin		S	Transplacental	Maternal Dose: Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18135858	EXPEDITED (15-DAY)		OT	NVSC2020ES218495		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Hydroxychloroquine			S	Oral	200 Mg, Q12h (400 Mg C/12h Dc Y 200mg C/12 Mant)		Novartis
	Hydroxychloroquine			S				Novartis
	Azithromycin			S	Oral	250 Mg, Q24h (500mg Dosis Choque Y 250 Mg C/24h Mantenimiento)		Not Reported
	Azithromycin			S				Not Reported
	Dexametasona			S	Intravenous (not otherwise specified)	6 Mg, Q24h (6mg C/24)		Not Reported
	Dexametasona			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G, Q24h (2g/24h)		Not Reported
	Ceftriaxona			S				Not Reported
	Midazolam			C	Unknown	Unk		Not Reported
	Fentanilo			C	Unknown	Unk		Not Reported
	Enoxaparina			C	Unknown	Unk		Not Reported
	Cisatracurio			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Omeprazol			C	Unknown	Unk		Not Reported
	Enalapril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18168165	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016136		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown	200 Milligram		Apotex
	Leflunomide	S	Unknown	20 Milligram		Apotex
	Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18173350	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202008007973			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis Crisis; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg, Bid, Every 12 Hour Daily (On Day 02)		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Tid (Q8h) Via Og Tube, (On Day 03 To 08)		Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	,(On Day 01)500 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd Via Og Tube, (On Day 02 To 05)		Not Reported
	Immunoglobulin I.V			C	Intravenous (not otherwise specified)	Unk Unk, Monthly		Not Reported
	Immunoglobulin I.V			C	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Azathioprine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18176024	EXPEDITED (15-DAY)		OT	CA-ACCORD-196168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Leflunomide	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Humira	S		Subcutaneous	Not Reported
	Enbrel	S			Not Reported
	Desoximetasone	C			Not Reported
	Rituximab	S		Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18196414	EXPEDITED (15-DAY)		OT	CA-ACCORD-197103		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Etanercept			S				Not Reported
	Celebrex			S				Not Reported
	Arava			S				Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Accord
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18196907	EXPEDITED (15-DAY)		OT	CA-ACCORD-197188		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Accord
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Oral			Not Reported

Leflunomide	S	Unknown		Not Reported
Metaraminol	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Cimzia	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Kineret	S	Unknown		Not Reported
Leflunomide	S	Oral	1 Every 1 Days	Not Reported
Prednisone	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Methotrexate	S	Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18198817	EXPEDITED (15-DAY)		OT	CA-ACCORD-196990		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous	Subcutanous Solution		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Humira	S	Subcutaneous	Subcutaneous Solution		Not Reported
Enbrel	S	Subcutaneous	1 Every 1 Weeks		Not Reported
Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Cimzia	S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Advil	C	Unknown			Not Reported
Prednisone	C	Oral	1 Every 1 Weeks		Not Reported
Tylenol	C	Unknown			Not Reported
Mefenamic Acid	C				Not Reported
Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Prednisone	C	Oral	1 Every 1 Weeks		Not Reported
Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18205706	EXPEDITED (15-DAY)		OT	NVSC2020IT233972		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Off Label Use; Tachyarrhythmia; Tachycardia; Vomiting; Weight Decreased	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211285	EXPEDITED (15-DAY)		OT	CA-ACCORD-197792		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Arava			S		2 Every 1 Weeks		Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown			Accord
	Methotrexate			S	Unknown			Accord
	Arava			S	Unknown	1 Every 2 Days		Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211405	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05118		70 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patients' Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211438	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05119		46 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patient'S Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211499	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05120		22 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patient'S Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211544	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05121		77 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S	Oral	0.4 Milligram, Qd	Lupin
	Arbidol	C	Oral	0.2 Gram, Tid	Not Reported
	Lopinavir/Ritonavir	C	Oral	500 Milligram, Bid	Not Reported
	Interferon Alfa	C		500 International Unit, Bid	Not Reported
	Thymalfasin	C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patient'S Response	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211582	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05122		48 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patient'S Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211760	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050679			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Amoxicillin+Clavulanic Acid			S	Oral	Unk Unk, Tid		Cadila
	Dolquine			S	Oral	200 Milligram, Qd		Not Reported
	Metronidazol [Metronidazole]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211781	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202008008183			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Rupture; Drug Intolerance; Fall; Joint Dislocation; Peripheral Ischaemia	Hydroxychloroquine			S	Unknown	Unk (Plaquenil)		Concordia
	Xarelto			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Tofacitinib			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Ami-2000			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18211954	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201812-004217			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Exposure During Pregnancy; Gestational Diabetes	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prograf			C		Unk		Not Reported
	Edirol			C		Unk		Not Reported
	Olopatadine Hydrochloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212077	EXPEDITED (15-DAY)		OT	IL-BAUSCH-BL-2020-024643		61 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute; Product Use In Unapproved Indication	Dexamethasone			S	Intravenous (not otherwise specified)			Bausch And Lomb
	Dexamethasone			S	Intravenous (not otherwise specified)	Tapered Dose		Bausch And Lomb

Azithromycin	S	Unknown		Not Reported
Azithromycin	S			Not Reported
Hydroxychloroquine	S	Unknown	Loading Dose Of 800 Mg On Day 1	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Zinc	S	Unknown		Not Reported
Zinc	S			Not Reported
Acetaminophen	S	Unknown	As Needed (1000 Mg On 4 Different Occasions)	Not Reported
Acetaminophen	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Anti-Interleukin-6 Receptor Antibody, 2 Doses Of 400 Mg Administered Intravenously	Not Reported
Tocilizumab	S			Not Reported
Enoxaparin	S	Unknown		Not Reported
Enoxaparin	S			Not Reported
Lopinavir/Ritonavir	S	Unknown	200 Mg/50 Mg	Not Reported
Lopinavir/Ritonavir	S			Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)		Not Reported
Pantoprazole	S			Not Reported
Ciprofloxacin	S	Intravenous (not otherwise specified)		Not Reported
Clindamycin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212110	EXPEDITED (15-DAY)		OT	CA-ACCORD-198260		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported

Naproxen	S		2 Every 1 Days		Not Reported
Orencia	S	Subcutaneous	1 Every 1 Months		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous,1 Every 1 Months		Not Reported
Sulfasalazine	S		2 Every 1 Days		Not Reported
Celebrex	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212113	EXPEDITED (15-DAY)		OT	CA-ACCORD-198262		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S				Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S				Not Reported
	Arava			S				Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212300	EXPEDITED (15-DAY)		DS, HO	CA-ACCORD-198173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Erythematosus; Wheelchair User	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Arava	S			Not Reported
	Prednisone	C			Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212302	EXPEDITED (15-DAY)		OT	CA-ACCORD-198126		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Methotrexate			S	Unknown			Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Prefilled Syringe		Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212304	EXPEDITED (15-DAY)		OT	CA-ACCORD-198189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Arava			S	Oral	1 Every 3 Weeks		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Hydroxychloroquine	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	1 Every 1 Days	Not Reported
	Arava	S	Oral	2 Every 1 Weeks	Not Reported
	Arava	S	Unknown	2 Every 1 Weeks	Not Reported
	Arava	S	Unknown	3 Every 1 Weeks	Not Reported
	Methotrexate	S	Intramuscular	1 Every 1 Weeks	Accord
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Accord
	Methotrexate	S	Intramuscular	1 Every 1 Days	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212310	EXPEDITED (15-DAY)		OT	CA-ACCORD-198122		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212311	EXPEDITED (15-DAY)		OT	CA-ACCORD-198121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212312	EXPEDITED (15-DAY)		OT	CA-ACCORD-198124		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	1 Every 24 Hours		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212313	EXPEDITED (15-DAY)		OT	CA-ACCORD-198127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Arava			S	Unknown	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212457	EXPEDITED (15-DAY)		OT	CA-ACCORD-197838		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Methotrexate			S		Frequency:1 Every 1 Weeks		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S		Frequency: 1 Every 1 Days		Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		Frequency : 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212463	EXPEDITED (15-DAY)		OT	CA-ACCORD-197837		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Viral Upper Respiratory Tract Infection	Methotrexate			S	Oral	Frequency: 1 Every 1 Weeks		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Frequency:2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	Frequency: 2 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212739	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020032954			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cortisone Acetate			S		25 Milligram		Not Reported
	Cortisone Acetate			S		25 Milligram		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral	25 Milligram		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported

Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous	4 Milligram	Not Reported
Hydroxychloroquine	S			Not Reported
Leflunomide	S			Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Orencia	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Pseudoephedrine Hcl	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S			Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfathalidine	S			Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Topical	Unk	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18212984	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335553			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg For The First Day		Pfizer
	Azithromycin			S		250 Mg For The Subsequent Days		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213382	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335546			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg For The First Day		Pfizer
	Azithromycin			S		250 Mg For The Subsequent Days		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213383	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335551			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg For The First Day		Pfizer
	Azithromycin			S		250 Mg For The Subsequent Days		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213384	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335545			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg For The First Day		Pfizer
	Azithromycin			S		250 Mg For The Subsequent Days		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213386	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335550			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication	Azithromycin		S	500 Mg For The First Day	Pfizer
	Azithromycin		S	250 Mg For The Subsequent Days	Pfizer
	Hydroxychloroquine		S	200 Mg, 3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213387	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335544			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg For The First Day		Pfizer
	Azithromycin			S		250 Mg For The Subsequent Days		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18214005	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA202008006543		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Menstrual Disorder; Nasopharyngitis; Nausea; Pain; Thrombosis; Uterine Disorder; Weight Decreased; Weight Increased	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Coumadin			S	Unknown	Unk, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unknown		Not Reported
	Metformin			S	Unknown	Unk, Unknown		Not Reported
	Metformin			S				Not Reported
	Prednisone			S	Unknown	Unk, Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unknown		Not Reported
	Azathioprine Sodium			C	Unknown	Unk, Unknown		Not Reported
	Methotrexate			C	Unknown	Unk, Unknown		Not Reported
	Xarelto			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18214154	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020335004		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Trimethoprim Sulfamethoxazole			C		Unk		Not Reported
	Tacrolimus			C		5 Mg, 2x/Day		Not Reported
	Tacrolimus			C		2.5 Mg, 2x/Day (Reduction)		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	60 Mg, 1x/Day (High Dose)		Not Reported
	Cefepime			C		Unk		Not Reported
	Mycophenolic Acid			C		250 Mg, 2x/Day		Not Reported
	Levofloxacin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18214500	EXPEDITED (15-DAY)		HO	FR-009507513-2008FRA012807		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Tienam 500mg/500mg, Poudre Pour Perfusion			S	Intravenous drip	Not Stated		Merck
	Linezolid			S	Intravenous drip	Not Stated		Not Reported
	Plaquenil			S	Oral	Not Stated		Not Reported
	Tazocilline			S	Intravenous drip	Not Stated		Not Reported
	Azithromycin			S	Oral	Not Stated		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18214647	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200839355		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Tacrolimus			S	Oral	2 Mg 2 Df Every 1 Day		Not Reported
	Tacrolimus			S	Oral	3 Mg 2 Df Every 1 Day		Not Reported
	Tacrolimus			S	Oral	3 Mg 2 Df Every 1 Day		Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18215171	EXPEDITED (15-DAY)		DE	CN-AMNEAL PHARMACEUTICALS-2020-AMRX-02612		64 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Fungal	Hydroxychloroquine Sulfate			S	Unknown	0.2 Gram, Daily		Amneal
	Methylprednisolone Sodium Succinate			S	Unknown	24 Milligram, Daily		Amneal
	Cyclosporine			S	Unknown	50 Milligram, 2 /Day		Not Reported
	Amlodipine			C	Unknown	5 Milligram, Qd		Not Reported
	Febuxostat			C	Unknown	40 Milligram, Qd		Not Reported
	Sodium Bicarbonate			C	Unknown	0.5 Gram, 3 /Day		Not Reported
	Warfarin			C	Unknown	2.5 Milligram, Qd		Not Reported
	Torasemide			C	Unknown	10 Milligram, Qd		Not Reported
	Potassium Chloride			C	Unknown	0.5 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18215706	EXPEDITED (15-DAY)		OT	CA-ACCORD-197822		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Naproxen			C	Unknown			Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	13517171	EXPEDITED (15-DAY)		DS, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038205		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Paracetamol	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported

Apo-Prednisone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Sarilumab	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Cetrizine	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone	S	Oral		Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported

Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Cetrizine	S	Unknown	10 Milligram	Not Reported
Diclofenac	S	Unknown		Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	17159637	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1122784			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect	Spasmolyt			S	Unknown	30 Milligram, Qd(30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1)		Mylan
	Spasmolyt			S	Unknown	1 Dosage Form, Qd		Mylan
	Spasmolyt			S	Unknown	15 Milligram, Qd		Mylan

Incomplete; Visual Impairment	Spasmolyt	S	Unknown	30 Milligram, Qd	Mylan
	Pregabalin Mylan	S	Unknown	1 Dosage Form, Tid (1-1-1) 1 Dosage Form	Mylan
	Pregabalin Mylan	S	Unknown	300 Milligram, Qd (100 Milligram, Tid)	Mylan
	Omeprazole	S	Oral	1 Dosage Form, Bid(1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12)	Mylan
	Omeprazole	S	Oral	40 Milligram, Qd (20 Milligram)	Mylan
	Ramipril	S	Oral	1 Dosage Form, Bid	Mylan
	Ramipril	S	Unknown	5 Milligram, Qd	Mylan
	Ambrisentan	S	Oral	1 Dosage Form, Qd	Mylan
	Ambrisentan	S	Unknown	30 Milligram, Qd	Mylan
	Sildenafil	S	Unknown	60 Milligram, Qd (60 Milligram, Daily Dose)	Mylan
	Eliquis	S	Unknown	1 Df, Bid (1 – 0 - 1)	Mylan
	Eliquis	S	Unknown	5 Milligram, Qd (2.5 Milligram, Bid)	Mylan
	Roactemra	S	Subcutaneous	162 Milligram, Qw (162 Milligram, Qwk)	Mylan
	Roactemra	S	Subcutaneous	162 Milligram, Qw	Mylan
	Roactemra	S	Unknown	162 Unk	Mylan
	Volibris	S	Oral	30 Milligram, Qd	Mylan
	Volibris	S	Oral	1 Dosage Form, Qd	Mylan
	Lyrica	S	Unknown	300 Milligram, Qd(100 Milligram, Tid)	Mylan
	Quensyl	S	Unknown	40 Milligram, Qd, (20 Mg Bid)	Mylan
	Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Mylan
	Quensyl	S	Unknown	1 Dosage Form, Bid (1-0-1)	Mylan

Apixaban	S	Unknown	5 Milligram, Qd(2.5 Milligram, Bid)		Mylan
Apixaban	S	Unknown	5 Milligram, Qd(2.5 Milligram, Bid)		Mylan
Apixaban	S	Unknown	2 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	17688626	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002981			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Off Label Use; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Not Reported
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Loxen (Loxoprofen Sodium)			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Movicol			S		2 Dosage Form Bag		Not Reported
	Paracetamol			C		Unk		Not Reported
	Paracetamol			C				Not Reported
	Lasilix			C		Unk		Not Reported
	Novorapid			C		Unk		Not Reported
	Doliprane			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	17691529	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-			Unknown	MEX

202003003107

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Cancer	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Orally Every 24 Hours		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	17718033	EXPEDITED (15-DAY)		HO, LT, OT	IT-ACCORD-179592		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Creatinine Increased; Coronavirus Infection; Diarrhoea; Drug Interaction; Drug Level Above Therapeutic; Glomerular Filtration Rate Abnormal; Nausea; Pneumonia; Vomiting	Tacrolimus			S		Bid, 3 Mg Bid		Accord
	Ceftriaxone			S				Not Reported
	Lopinavir/Ritonavir			S		400mg/100mg Bid		Not Reported
	Hydroxychloroquine			S		Bid		Not Reported
	Methylprednisolone			S		6.5 Mg Daily		Not Reported
	Allopurinol			C				Not Reported
	Atorvastatin			C				Not Reported
	Ramipril			C				Not Reported
	Omeprazole			C				Not Reported
	Tacrolimus			S		Bid, 3 Mg Bid		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	17966404	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-249236		25 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Plaquenil			S	Oral	200 Milligram, Daily		Not Reported
	Augmentin			S	Oral	1 Gram, Daily		Not Reported
	Augmentin			S	Oral	1 Gram		Not Reported

Augmentin	S	Oral	1 Gram		Not Reported
Clexane	C	Subcutaneous	1 Dosage Form, Daily		Not Reported
Clexane	C	Subcutaneous	1 Dosage Form		Not Reported
Clexane	C	Subcutaneous	1 Dosage Form		Not Reported
Dicloreum 75 Mg/3 Ml Soluzione Iniettabile Per Uso Intramuscolare	C	Intramuscular	1 Dosage Form, In Total		Not Reported
Dicloreum 75 Mg/3 Ml Soluzione Iniettabile Per Uso Intramuscolare	C	Intramuscular	1 Dosage Form		Not Reported
Dicloreum 75 Mg/3 Ml Soluzione Iniettabile Per Uso Intramuscolare	C	Intramuscular	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	17974043	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200637710		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxyquinoline Sulfate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Oral			Not Reported

	Tacrolimus	S	Oral		Not Reported
	Tacrolimus	S	Oral		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Prograf	S	Oral		Not Reported
	Prograf	S	Oral		Not Reported
	Hydroxychloroquine	S			Not Reported
	Methotrexate Sodium	S			Not Reported
	Imuran /00001501/	C	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18046487	EXPEDITED (15-DAY)			JP-ADVANZ PHARMA-202007007199			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet		Concordia
	Prednisolone			C		Unk		Not Reported
	Gaster			C		Unk		Not Reported
	Gaster			C				Not Reported
	Edirol			C		Unk		Not Reported
	Edirol			C				Not Reported
	Mohrus			C		Unk		Not Reported
	Bonoteo			C		Unk		Not Reported
	Bonoteo			C				Not Reported
	Sg			C		Unk		Not Reported
	Hirudoid			C		Unk		Not Reported
	Keratinamin			C		Unk		Not Reported
	Juvela			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18068570	EXPEDITED (15-DAY)		OT	NVSC2020PE208572			Male	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Maternal Dose - Unk		Novartis
	Meropenem			S	Transplacental	Maternal Dose - Unk		Not Reported
	Vancomycin			S	Transplacental	Maternal Dose - Unk		Not Reported
	Oseltamivir			S	Transplacental	Maternal Dose - Unk		Not Reported
	Azithromycin			S	Transplacental	Maternal Dose - Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18096528	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP014685		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	10 Milligram		Apotex
	Cefazolin			S	Intramuscular	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Viread			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18179875	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016194			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Unknown	Unk		Apotex
	Arthrotec			S	Oral	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.O.Wk.		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Q.Wk.		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q.3w		Not Reported
	Sulfasalazine			S	Oral	2 Gram, Qd		Not Reported
	Mefenamic Acid			C	Oral	200 Milligram		Not Reported
	Tylenol			C	Unknown	650 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18189941	EXPEDITED (15-DAY)		DE	US-SLATE RUN PHARMACEUTICALS-20US000263			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypercoagulation; Rash	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Piperacillin + Tazobactam			S	Unknown			Not Reported
	Oxygen			C	Nasal	4 Litre Per Minute		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18199201	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2020325973		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Off Label Use; Oxalosis; Product Use In Unapproved Indication; Toxicity To Various Agents	Azithromycin	S		500 Mg, Daily (D: 5)	Pfizer
	Linezolid	S		Unk	Pfizer
	Meropenem	S		Unk	Pfizer
	Piperacillin/Tazobactam	S		Unk	Pfizer
	Vitamin C [Ascorbic Acid]	S	Intravenous (not otherwise specified)	50 Mg/Kg, 4x/Day (High Dose)	Not Reported
	Vitamin C [Ascorbic Acid]	S	Intravenous (not otherwise specified)	160 Mg (Total Dose)	Not Reported
	Hydroxychloroquine	S		400 Mg, 2x/Day For 24 Days	Not Reported
	Darunavir And Cobicistat	S		Unk, Daily (800/150mg, Daily For 7 Days)	Not Reported
	Lopinavir/Ritonavir	S		200/50 Mg	Not Reported
	Ceftriaxone	S		Unk	Not Reported
	Daptomycin	S		Unk	Not Reported
	Oxacillin	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18215504	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-258624		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypotension	Doxycycline			S	Oral	200 Milligram		Sun
	Doxycycline			S				Sun
	Hydroxychloroquine			S	Oral	400 Milligram		Ipca
	Vancomycin Hydrochloride			S	Unknown	Unk		Not Reported
	Aztreonam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18215506	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-249779		72 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Lopinavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18215513	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-258625		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Betamethasone			S	Unknown	Unk		Taro
	Nitric Oxide			S		Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18215529	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-258840		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Exposure During Pregnancy	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Azithromycin			S	Oral	250 Milligram, Daily		Sun
	Hydroxychloroquine			S	Oral	400 Milligram, 1dose/12hour		Sun
	Hydroxychloroquine			S	Oral	200 Milligram, 1dose/12hour		Sun
	Methylprednisolone			S	Intravenous (not otherwise specified)	40 Milligram, 1dose/12hour		Not Reported
	Ceftriaxone			S	Intravenous (not	1 G Single Dose		Not Reported

			otherwise specified)		
	Tocilizumab	S	Unknown		Not Reported
	Lovenox	S	Unknown	40 Milligram, Daily	Not Reported
	Betamethasone	S	Intramuscular	12mg Im, 2 Doses 24 Hours Apart	Not Reported
	Augmentin	C	Oral	875 Milligram, 1dose/12hour	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18215699	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-27185		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18215978	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246897		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	200 Mg B.I.D.		Sun
	Azithromycin			S	Unknown	500 Milligram, Qd		Sun

Lopinavir/Ritonavir	S	Unknown	200/50 Mg B.I.D		Not Reported
Ceftriaxone	S	Unknown	2 G Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216180	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1821343		74 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Haematocrit Decreased; Off Label Use; Platelet Count Decreased; Purpura; Soft Tissue Infection	Hydroxychloroquine			S	Unknown			Teva
	Enoxaparin			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown	200/50mg Two Tablets		Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Ruxolitinib			S	Unknown	2 Tablets/Day For 2 Days, And 4 Tablets For 3 Days		Not Reported
	Tocilizumab			S	Subcutaneous	2 Injections Per 2 Cycles A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216236	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1821337		72 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobinuria; Haemolytic Anaemia; Off Label Use	Hydroxychloroquine			S	Unknown			Teva
	Lopinavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216519	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1821344		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Drug Interaction; Drug Level Increased; Haematocrit Decreased; Haemoglobin	Hydroxychloroquine			S	Unknown			Teva
	Enoxaparin			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown	2 Dosage Forms Daily; 200mg/50mg Two Tablets		Not Reported

Decreased; Off Label Use; Oral Herpes					Twice Daily	
	Ruxolitinib		S	Unknown	10 Milligram Daily; 2 Tablets/Day	Not Reported
	Ruxolitinib		S	Unknown	Dose Doubled	Not Reported
	Ruxolitinib		S	Unknown	5 Milligram Daily;	Not Reported
	Levothyroxine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216854	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05116		54 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patients' Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216868	EXPEDITED (15-DAY)		OT	CA-ACCORD-198263			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Methotrexate			S		1 Every 1 Weeks		Accord
	Sulfasalazine			S		2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S		1 Every 24 Hours		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216917	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-05196		82 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216930	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-05201		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Azathioprine			C	Unknown	100 Milligram, Qd		Not Reported
	Mesalazine			C	Oral	Unk		Not Reported
	Infliximab			C	Oral	5 Milligram/Kilogram Every 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216931	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05117		7 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week		Not Reported

According To Patients' Response

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216969	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820454		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216980	EXPEDITED (15-DAY)		HO, LT, OT	GR-LUPIN PHARMACEUTICALS INC.-2020-05199		62 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Covid-19 Pneumonia; Drug Effective For Unapproved Indication; Off Label Use; Renal Impairment; Respiratory Failure	Methylprednisolone			S	Unknown	6 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Rituximab			S	Unknown	375 Milligram/Sq. Meter, Four Weekly Doses		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Milligram/Sq. Meter, Three Monthly Doses (Stop Drug In Oct-2019)		Not Reported
	Prednisolone			S	Unknown	0.75 Milligram/Kilogram Every 3 Weeks		Not Reported

	Prednisolone		S	Unknown	Unk, Tapering Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18216983	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05095		30 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	0.4 Milligram, Qd		Lupin
	Arbidol			C	Oral	0.2 Gram, Tid		Not Reported
	Lopinavir/Ritonavir			C	Oral	500 Milligram, Bid (6-16 Days)		Not Reported
	Interferon Alfa			C		500 International Unit, Bid		Not Reported
	Thymalfasin			C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patients' Response		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217012	EXPEDITED (15-DAY)		LT, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05100		67 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Respiratory Disorder	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	80 Milligram, Unk		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Subcutaneous	50 International Unit/Kilogram, Qd		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217013	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05115		53 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S	Oral	0.4 Milligram, Qd	Lupin
	Arbidol	C	Oral	0.2 Gram, Tid	Not Reported
	Lopinavir/Ritonavir	C	Oral	500 Milligram, Bid	Not Reported
	Interferon Alfa	C		500 International Unit, Bid	Not Reported
	Thymalfasin	C	Intramuscular	1.6 Milligram, Day To Twice Per Week According To Patients' Response	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217306	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820310		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217343	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820365		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217358	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-259843		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Drug Intolerance	Azithromycin			S	Unknown			Not Reported
	Mesalazine			S	Oral	Unk		Sun
	Hydroxychloroquine			S	Unknown			Ipca
	Infliximab			S	Oral	5 Milligram/Kilogram		Not Reported
	Azathioprine			S	Unknown	100 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217675	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1075532		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Heparin			S	Unknown	5000 Units		Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217818	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1075210		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Propofol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217922	EXPEDITED (15-DAY)		OT	NVSC2020CN239577		64 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Product Use In Unapproved Indication	Cyclosporine			S	Unknown	50 Mg, Bid		Novartis
	Methylprednisolone			S	Unknown	24 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	0.2 G, Bid		Not Reported
	Amlodipine			S	Unknown	5 Mg, Qd		Not Reported
	Febuxostat			S	Unknown	40 Mg, Qd		Not Reported
	Sodium Bicarbonate			S	Unknown	0.5 G, Tid		Not Reported
	Warfarin			S	Unknown	2.5 Mg, Qd		Not Reported
	Torasemide			S	Unknown	10 Mg, Qd		Not Reported
	Potassium Chloride			S	Unknown	0.5 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218259	EXPEDITED (15-DAY)		LT, OT	CA-PFIZER INC-2020335524			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Gastrointestinal Haemorrhage	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S				Pfizer
	Leflunomide			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Rabeprazole			C				Not Reported
	Folic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218349	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05109			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Low Birth Weight Baby; Neonatal Respiratory Distress Syndrome; Premature Baby	Hydroxychloroquine		S	Transplacental	Unk	Lupin
	Azithromycin		S	Transplacental	Unk	Lupin
	Ceftriaxone		S	Transplacental	Unk	Lupin
	Betamethasone		S	Transplacental	Unk	Lupin
	Tocilizumab		S	Transplacental	400 Milligram Once	Not Reported
	Heparin		S	Transplacental	Unk	Not Reported
	Magnesium		S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218370	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05101		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Hypertriglyceridaemia; Off Label Use; Premature Delivery; Pulmonary Embolism; Transaminases Increased	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram, Single		Not Reported
	Heparin			S	Unknown	Unk		Not Reported
	Magnesium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218551	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1075354		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	Unk		Mylan
	Plaquenil /00072603/			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18219518	EXPEDITED (15-DAY)		OT	NVSC2020ES240420		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral	200-400 Mg		Novartis
	Prednisone			S	Oral	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18219535	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820624			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Topicort			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18219579	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	14243135	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021933		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	10 Mg, Q.O.D.		Apotex
	Leflunomide			S	Unknown	5 Mg, Q.O.D.		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	0.8 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	10 Milligram		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	10 Milligram	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	16008854	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016510		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Inflammation; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sinusitis; Swelling; Synovitis;	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

Simponi	S	Subcutaneous		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Cortisone Acetate	S	Topical		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]]	S	Unknown	400 Milligram Daily;	Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S		2 Gram Daily;	Not Reported
Sulfasalazine	S	Subcutaneous	2 Gram Daily;	Not Reported
Topicort Mild	S	Oral		Not Reported
Topicort Mild	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S			Not Reported
Apo Folic	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram Daily;	Not Reported
Sarilumab	S	Unknown		Not Reported
Sarilumab	S			Not Reported
Stelara	S	Unknown		Not Reported
Sulfathalidine	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
Xeljanz	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported

Methotrexate Sodium	S	Oral	Not Reported
Reactine [Cetirizine]	S	Unknown	Not Reported
Cortisone	S	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported
Atasol [Paracetamol]	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17075620	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025078			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Pregabalin			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Unk (1 Every 4 Weeks)		Not Reported
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Oral	Unk, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported

Enbrel	S	Unknown	50 Milligram		Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
Imuran /00001501/	S	Unknown	Unk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Piroxicam	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17526155	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07599		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy;	Infliximab			S	Unknown	Unknown		Not Reported

Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired Gastric Emptying; Influenza; Off Label Use; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown,	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not		Not Reported

			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown		Not Reported
	Sulfasalazine	S	Oral	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported
	Meloxicam	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17570316	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008939		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Peripheral Swelling; Pneumonia Viral; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arthrotec	C	Oral	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Imuran /00001501/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17722899	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Oral			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Cortisone Acetate	S	Topical	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S		Not Reported
Etanercept	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown	Not Reported

	Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17726275	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020963		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Pyrexia; Respiratory Disorder	Omeprazole			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Aurobindo
	Omeprazole			S	Intravenous (not otherwise specified)	40 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	1200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Midazolam			S	Intravenous (not otherwise specified)	5 Dosage Form, Once A Day (5 Mg/Ml, Qd)		Not Reported
	Lovenox			S	Subcutaneous	0.6 Milliliter, Once A Day		Not Reported
	Loxen (Nicardipine)			S	Intravenous (not otherwise specified)	30 Milligram, Once A Day		Not Reported
	Movicol			S	Unknown	2 Dosage Form (2 Df Bag)		Not Reported
	Diffu K			C	Unknown	3.6 Gram, Once A Day		Not Reported
	Diffu K			C				Not Reported
	Doliprane			C	Unknown	Unk		Not Reported
	Doliprane			C				Not Reported
	Paracetamol			C	Unknown	4 Gram, Once A Day		Not Reported
	Paracetamol			C				Not Reported
	Lasilix			C	Unknown	30 Milligram, Once A Day		Not Reported
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17792459	EXPEDITED (15-DAY)		LT, OT	JP-HQ SPECIALTY-JP-2020INT000054		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrioventricular Block First Degree; Covid-19 Pneumonia; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Ventricular Fibrillation; Viral Myocarditis	Dexmedetomidine Hydrochloride			S	Unknown	Unk		Hq Specialty
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Favipiravir			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Ciclesonide			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	1 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17920594	EXPEDITED (15-DAY)		LT, OT	NVSC2020FR173128		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate			S	Other	1200 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Not Reported
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Not Reported
	Movicol			S	Other	2 Df Bag		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Lasilix			C	Other	30 Mg, Qd		Not Reported

Paracetamol	C	Other	4 G, Qd		Not Reported
Paracetamol	C				Not Reported
Doliprane	C	Unknown	Unk		Not Reported
Doliprane	C				Not Reported
Novorapid	C	Intravenous (not otherwise specified)	Unk		Not Reported
Diffu K	C	Other	3.6 G, Qd		Not Reported
Diffu K	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17939955	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1057633		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; C-Reactive Protein Increased; Coronavirus Infection; Drug Interaction; Drug Level Increased; Gastrointestinal Disorder; Nephropathy Toxic; Off Label Use; Renal Failure	Tacrolimus			S	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Qd, 200/100mg (5 Day)		Mylan
	Lopinavir/Ritonavir			S	Oral	Unk, Bid (200/100 Mg)		Mylan
	Prednisone			S	Unknown	Unk		Mylan
	Prednisone			S		Unk		Mylan
	Mycophenolic Acid			S		Unk (Dose Reduce)		Mylan
	Mycophenolic Acid			S		Unk (Dose Reduce)		Mylan
	Hydroxychloroquine			S	Oral	400 Milligram (0.5 Day)		Mylan
	Hydroxychloroquine			S	Oral	800 Milligram, Qd (400 Milligram (0.5 Day)		Mylan
	Hydroxychloroquine			S	Oral	200 Milligram (0.5 Day)		Mylan
	Hydroxychloroquine			S	Oral	800 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17974136	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2020251212		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome; Off Label Use; Product Use In Unapproved Indication	Azithromycine	S	Oral	500 Mg	Pfizer
	Azithromycine	S	Oral	250 Mg, Daily	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	Unk (32mg/42ml)	Not Reported
	Cefotaxime Sodium	C		2000 Mg, 3x/Day	Not Reported
	Bipreterax [Indapamide;Perindopril Arginine]	C	Oral	Unk (1 At The Morning)	Not Reported
	Janumet	C		2 Df (1 Tablet At The Morning And 1 Tablet At The Evening)	Not Reported
	Suxamethonium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Etomidate	C	Intravenous bolus	30 Mg	Not Reported
	Lovenox [Enoxaparin Sodium]	C	Subcutaneous	4000 Iu	Not Reported
	Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Rovamycine [Spiramycin Adepate]	C	Intravenous (not otherwise specified)	6 Miu (Administered Once)	Not Reported
	Amlodipine	C		10 Mg (1 Tablet At The Evening)	Not Reported
	Sufentanil	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18040641	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR015747			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Blood Count Abnormal; Bronchiolitis;	Salbutamol Sulphate			S		Unk (As Required)		Glaxosmithkline
	Zopiclone			S		Unk, As Required		Glaxosmithkline

Carcinoid Tumour Pulmonary; Diarrhoea; Disease Recurrence; Dyspnoea; Hypoxia; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Musculoskeletal Discomfort; Oxygen Saturation Decreased; Peripheral Swelling; Productive Cough; Sleep Disorder Due To A General Medical Condition; Sputum Discoloured; Systemic Lupus Erythematosus; Therapeutic Product Effect Incomplete; Wheezing	Azathioprine	S	200 Mg, Qd	Glaxosmithkline
	Telmisartan	S	80 Mg, Qd	Glaxosmithkline
	Flu Vaccine	S		Glaxosmithkline
	Spiriva Respimat	S	2 Puff(S), Qd	Not Reported
	Lanreotide	S	Unk	Not Reported
	Symbicort	S	2 Puff(S), Bid (200/6)	Not Reported
	Prednisone	S	5 Mg, Qd	Not Reported
	Plaquenil	S	400 Mg, Qd	Not Reported
	Alendronate	S	70 Mg, We	Not Reported
	Tecta	S	40 Mg, Qd	Not Reported
	Lyrica	S	150 Mg, Bid	Not Reported
	Cymbalta	S	20 Mg, Qd	Not Reported
	Nucala	C	Unk	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18053825	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP013766		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	640 Milligram		Not Reported
	Actemra			S	Unknown	640 Milligram, Q.Wk.		Not Reported
	Arava			S	Oral	Unk Unk, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Unknown	200 Milligram, Q.O.Wk.		Not Reported

Incomplete	Certolizumab Pegol	S	Unknown	200 Milligram, Q.O.Wk.	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Milligram, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	400 Milligram, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	400 Milligram, Q.Wk.	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Q.Wk.	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil Sulfate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q.Wk.	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18054912	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP008331			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Leflunomide			S	Unknown	20 Mg,Daily, Started Prior		Apotex

Intolerance; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure				To 2013	
	Cyclosporine	S	Unknown	Unk	Apotex
	Doxycycline	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Azathioprine	S	Unknown	150 Mg,Daily(Started Prior To 2013)	Apotex
	Bromocriptine	S	Unknown	Unk	Not Reported
	Methotrexat /00113801/	S	Unknown	Unk	Not Reported
	Pamidronate	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Milligram, B.I.Wk. (Started Prior To 2013)	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.	Not Reported
	Ustekinumab	S	Unknown	Unk	Not Reported
	Colchicine	S	Unknown		Not Reported
	Gold	S	Unknown	Unk	Not Reported
	6-Mercaptopurine Monohydrate	C	Unknown	Unk	Not Reported
	Tenoxicam	C	Unknown	Unk	Not Reported
	Dilaudid	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Ustekinumab	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Bromocriptine	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Colchicine	C	Unknown	Unk	Not Reported
	Doxycycline	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Pamidronate Disodium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18090055	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP014464			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18198707	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-067165			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported

Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous	50 Milligram, Qd		Not Reported
	Gammagard	S	Unknown	Unk		Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Infliximab	S	Unknown	5 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Naproxen	S	Unknown			Not Reported
	Prednisone	S	Oral	10 Milligram, Qd		Not Reported
	Prednisone	S	Oral	3 Milligram		Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone Hexacetonide	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18211589	EXPEDITED (15-DAY)		DS, OT	CA-COLGATE PALMOLIVE COMPANY-20200801616			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal	Periogard Unspecified			S	Buccal			Colgate
	Chlorhexidine Unspecified			S	Unknown	Unk		Colgate
	Chlorhexidine Unspecified			S	Topical	Unk		Colgate
	Chlorhexidine Gluconate Unspecified			S	Oral			Colgate
	Folic Acid			S	Unknown	5 Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Fosamax			S	Oral			Not Reported

Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Leflunomide	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Topicort [Triamcinolone Acetonide]	S	Cutaneous		Not Reported
	Cetirizine	S	Unknown	10 Mg	Not Reported
	Cetirizine	S	Unknown	10 Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Mg	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Methotrexate	S	Oral	25 Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	3011.2 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	2912 Mg	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Oral		Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Oxycodone	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Desoximetasone	S	Oral		Not Reported
Arava	S	Oral	20 Mg	Not Reported
Xeljanz	S	Unknown	10 Mg	Not Reported
Cortisone	S	Topical	25 Mg	Not Reported
Pseudoephedrine	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Oral	7.5 Mg	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Oxycodone Terephthalate	S	Unknown		Not Reported
Tylenol [Paracetamol]	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Tylenol With Codeine	C	Unknown		Not Reported
Desogestrel/Ethinylestradiol	C	Unknown		Not Reported
Ibuprofen	C	Unknown		Not Reported
Pantoloc [Pantoprazole]	C	Unknown		Not Reported
Cetrizine	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220221	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220222	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820335			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220244	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820417			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220245	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220646	EXPEDITED (15-DAY)		OT	CA-SA-2020SA230928			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Lymphoma	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Methotrexate Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220704	EXPEDITED (15-DAY)		HO, OT	CN-ACCORD-198583		39 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Mycophenolic Acid			S		1.0 G, Bid		Not Reported
	Prednisone			S		10 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220868	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-258626			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Foetal Exposure During Pregnancy; Intraventricular Haemorrhage Neonatal; Low Birth Weight Baby; Neonatal Respiratory Distress Syndrome; Patent	Hydroxychloroquine			S	Transplacental			Sun
	Azithromycin			S	Transplacental			Sun
	Betamethasone			S	Transplacental			Taro
	Nitric Oxide			S	Transplacental			Not Reported
	Remdesivir			S	Transplacental			Not Reported

Ductus Arteriosus; Premature Baby	Tocilizumab		S	Transplacental	Not Reported
	Magnesium Sulfate		C	Unknown	Not Reported
	Propofol		C	Transplacental	Not Reported
	Propofol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220869	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259141			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Sun
	Azithromycin			S	Transplacental	Unk		Sun
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Tocilizumab			S	Transplacental	400 Milligram		Not Reported
	Heparin			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220871	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820608		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220875	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259140		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypertriglyceridaemia; Premature Delivery; Transaminases Increased	Hydroxychloroquine			S	Unknown	Unk		Sun
	Azithromycin			S	Unknown	Unk		Sun
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220988	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2020-05210		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Rabeprazole Sodium			S	Unknown	Unk		Lupin
	Metoclopramide Hydrochloroide			S	Unknown	Unk		Novel Labs
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Dihydrocodeine			C	Unknown	Unk		Not Reported
	Lactulose			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221022	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2020-05212		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Heparin			C	Subcutaneous	Unk (Low Molecular Weight)		Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221026	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039188		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin Hydrochloride			S	Unknown			Actavis
	Metformin Hydrochloride			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Cymbalta			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221069	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335548			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azithromycin			S		500 Mg (The First Day)		Pfizer
	Azithromycin			S		250 Mg (The Subsequent Days)		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221076	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020337189			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg For The First Day		Pfizer
	Azithromycin			S		250 Mg For The Subsequent Days		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221081	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC-2020338170			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Embolic Stroke; Encephalomalacia; Encephalopathy; Fall; Hypercapnia; Muscle Injury; Myopathy; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Respiratory Failure; Subarachnoid Haemorrhage; Tibia Fracture; Toxicity To Various Agents	Hydrocortisone			S		Every Morning		Pfizer
	Hydrocortisone			S		In The Afternoon		Pfizer
	Hydroxychloroquine			S		200 Mg, Cyclic (12 H)		Not Reported
	Hydroxychloroquine			S		Prolonged Hiatus		Not Reported
	Anakinra			C	Subcutaneous	100 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221092	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820721		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221437	NON-EXPEDITED			US-PFIZER INC-2020337792		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221527	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202008008341			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

	Hydroxychloroquine	S		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221528	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202008008342			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221941	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202008008347			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal; Malaise; Off Label Use	Hydroxychloroquine			S		Unk, (Plaquenil)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222337	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported

	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222493	EXPEDITED (15-DAY)		OT	FR-009507513-2008FRA014071		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Thrombocytopenia	Invanz			S	Intravenous drip	1 Gram		Merck
	Plaquenil			S	Oral	600 Milligram, Qd		Not Reported
	Zithromax			S	Oral	250 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222727	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820557			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Infliximab			S	Unknown	300 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222831	EXPEDITED (15-DAY)		OT	NVSC2020FR236545		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricular Dysfunction	Dabrafenib			S	Oral	300 Mg, Qd		Novartis
	Trametinib			S	Oral	2 Mg, Qd		Not Reported
	Plaquenil			S	Oral	1200 Mg, Qd		Not Reported
	Nivolumab			S	Intravenous (not otherwise specified)	(C1 18/10/2018 ; C2 13/11/2018 ; C3 04/12/2018) - (C1 01/03/2019 ; C2 01/04/2019) - (C1 06/05/2020 ;		Not Reported
	Ipilimumab			S	Intravenous (not otherwise specified)	(C1 18/10/2018 ; C2 13/11/2018 ; C3 04/12/2018)		Not Reported
	Cortancyl			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222864	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05347		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk		Lupin
	Methylprednisolone			S				Lupin
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222945	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820402		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Alendronate Sodium	S	Unknown			Actavis
	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Cetirizine Hydrochloride	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Unknown			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
	Topicort	S	Cutaneous			Not Reported
	Leflunomide	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223053	EXPEDITED (15-DAY)		HO, OT	IN-APPCO PHARMA LLC-2089324		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223429	NON-EXPEDITED			US-APPCO PHARMA LLC-2089326			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223607	NON-EXPEDITED			US-APPCO PHARMA LLC-2089331		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223711	NON-EXPEDITED			US-AMGEN-USASP2020142583		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Amjevita			S	Unknown	Unk		Amgen
	Amjevita			S				Amgen
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Not Reported
	Methotrexate Sodium			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline			S				Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223792	EXPEDITED (15-DAY)		OT	NVSC2020ES240409		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Oral	750 Mg, Qd		Not Reported
	Prednisone			S	Oral	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223965	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-068490		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricular Dysfunction	Nivolumab			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Ipilimumab			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Dabrafenib			S	Oral	300 Milligram, 1 Day Interval		Not Reported
	Plaquenil			S	Oral	1200 Milligram, 1 Day Interval		Not Reported
	Trametinib			S	Oral	2 Milligram, 1 Day Interval		Not Reported
	Cortancyl			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18224615	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-259724		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use;	Azithromycin			S	Oral	500 Milligram, Single ; In Total		Sun

Syncope	Azithromycin	S	Oral	250 Milligram, Qd	Sun
	Sotalol	S	Unknown	Unk	Sun
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	9459293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1162770		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased; Cataract; Cystitis; Drug Intolerance; Dry Mouth; Dyslipidaemia; Fall; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Osteoporosis; Painful Respiration; Pharyngeal Mass; Pneumonia; Poor Venous Access; Synovitis; Upper Limb Fracture; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Synthroid			C				Not Reported
	Flexeril			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Tylenol			C				Not Reported
	Folic Acid			C				Not Reported
	Garlic			C				Not Reported
	Methotrexate			C				Not Reported

	Sulfasalazine	C	Oral		Not Reported
	Naprosyn	C			Not Reported
	Calcium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	11565068	EXPEDITED (15-DAY)		DS, LT, OT	CA-009507513-1509CAN012569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Discomfort; Dizziness; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Fibromyalgia; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure	Fosamax			S	Oral	Unk		Merck
	Fosamax			S	Unknown	Route: Intra Corpus Cavernosum		Merck
	Fosamax			S	Unknown	Unk		Merck
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Unk; Solution Subcutaneous		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	20.0 Milligram, 1 Every 1 Days; Solution		Not Reported
	Methotrexate			S	Oral	25.0 Milligram		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
	Methotrexate			S	Oral	20.0 Milligram, 1 Every 1 Days		Not Reported
	Methotrexate			S	Intra-arterial	25 Unk		Not Reported
	Apo Prednisone			S	Unknown	5 Milligram		Not Reported
	Apo Prednisone			S	Unknown	Unk		Not Reported
	Apo Prednisone			S	Unknown	1 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qw		Not Reported

During Pregnancy; Musculoskeletal Stiffness; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Pericarditis; Prescribed Overdose; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; Wheezing; Wound	Enbrel	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Unknown	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg/0.8 Ml, Solution For Injection In Prefilled Syringe	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Plaquenil	S	Unknown	40 Milligram, Qd	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
	Reactine (Cetirizine Hydrochloride)	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day(S)	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Unknown	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, 1 Every 1 Day	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Day	Not Reported
	Apo Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Apo Folic Acid	S	Unknown	1, Unk	Not Reported
	Apo Folic Acid	S	Unknown	15 Unk	Not Reported

Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Zyrtec	S	Unknown	25 Milligram	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Mg, Q24h	Not Reported
Desoximetasone	S	Oral	Unk; Dosage Form: Not Specified	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride (+) Phenylephrine Hydrochloride	S	Unknown	10 Milligram, Qd	Not Reported
Cetirizine Hydrochloride (+) Phenylephrine Hydrochloride	S	Unknown	10 Milligram, Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Diclofenac Sodium	S	Unknown	Unk; Dosage Form Not Specified	Not Reported
Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	25.0 Milligram	Not Reported
Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk, Other	Not Reported
Topicort (Hydrocortisone Acetate)	S	Cutaneous	Unk; Dosage Form Not Specified	Not Reported
Folic Acid	S	Oral	500 Milligram Per Litre, Unknown	Not Reported
Folic Acid	S	Unknown	1.0 Milligram, Unknown	Not Reported

Folic Acid	S	Unknown	5.0 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk, Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	4000.0 Milligram, 1 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	4000.0 Milligram, 1 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk, Unknown	Not Reported
Prednisone	S	Unknown	Unk; Dosage Form: Not Specified	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Acetaminophen	S	Unknown	Unk, Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride (+) Phenylephrine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Oral	Unk	Not Reported

Topicort (Desoximetasone)	S	Other	Unk	Not Reported
Topicort (Desoximetasone)	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram, 1 Every 1 Days	Not Reported
Cortisone	S	Unknown	25 Milligram	Not Reported
Etanercept	S	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol	C	Unknown	Unk	Not Reported
Atasol	C			Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Prinivil	C	Unknown	Unk	Merck
Cholecalciferol	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zyrtec	C	Unknown	Unk	Not Reported
Tofacitinib	C	Unknown	Unk	Not Reported
Acetaminophen (+) Caffeine, Citrated (+) Codeine Phosphate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	12891035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Tooth Loss	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Methotrexate	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	4omg/0.8ml	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Zostavax	S	Subcutaneous	500 Milligram	Not Reported
	Zostavax	S	Subcutaneous	Unk	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	10 Mg, Bid	Not Reported
	Cortisone /00014602/	C	Unknown	Unk	Not Reported
	Diclofenac /00372302/	C	Subcutaneous	100 Mg, Unk	Not Reported
	Cortisone Acetate	C	Subcutaneous	Unk	Not Reported
	Desoximetasone	C	Oral	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Subcutaneous	Unk	Not Reported
	Desoximetasone	C	Subcutaneous	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	13058845	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015768		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Parenteral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Parenteral	25 Mg, 1 Every 4 Weeks		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	C	Unknown	Unk, Qd	Not Reported
	Azathioprine	C	Unknown	Unk Unk, Qd	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Minocycline	C	Unknown	Unk, Qd	Not Reported
	Prednisolone	C	Unknown	6 Mg, Qd	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	6 Mg, Bid	Not Reported
	Actemra	C	Unknown	Unk	Not Reported
	Cyclosporine	C	Unknown	Unk	Not Reported
	D-Penicillamine	C	Unknown	Unk	Not Reported
	Phenylbutazone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	13251533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006675		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis;	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	Unk (Therapy Duration: 129 Unit Unspecified)		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported

Stress	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	125 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Q.O.Wk.	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	6 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Prednisone	C	Oral	6 Milligram, Q.Wk.	Not Reported
	Prednisone	C	Oral	10 Milligram, Q.Wk.	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Dequalinium Chloride	C	Unknown	Unk	Not Reported
	Advil /00044201/	C	Unknown	Unk	Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	13254292	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006753		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex

Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	200 Milligram, Q.12h	Apotex
	Hydroxychloroquine	S	Oral	200 Milligram, Q.12h	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd, (Therapy Duration: 365 Unit Not Reported)	Apotex
	Apo-Leflunomide	S	Unknown	11.2 Mg, Qd (Therapy Duration: 365 Unit Not Reported)	Apotex
	Leflunomide	S	Unknown	20 Mg, Qd, Thepay Duration 365 Unit Not Reported	Apotex
	Sulfasalazine	S	Unknown	1 G, Qd	Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	20 Mg, Two Every Two Days	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Sodium Aurothiomalate	S	Parenteral	1 G, Qd	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Q.12h	Not Reported
	Prednisone	C	Oral	15 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	13957945	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017756		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Advil /00044201/			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ketorolac			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported
	Advil [Ibuprofen]			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	13969809	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP018054		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Colitis Microscopic; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Recurrence; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Finger Deformity; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infection; Joint Swelling; Laboratory Test Abnormal; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Nausea; Off Label Use; Osteoarthritis; Palpitations; Pneumonia; Pulmonary Fibrosis; Pulmonary Mass; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Endocervical	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram		Apotex
	Actemra			S	Endocervical	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, Therapy Diration 730 Unknown Unit		Not Reported
	Enbrel			S	Unknown	Unk, Therapy Duration 731 Unknown Unit		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported

Arthritis; Rheumatoid Factor Positive; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate	S	Subcutaneous	7.5 Milligram	Not Reported
	Methotrexate	S	Unknown	7.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Celebrex	S	Oral	200 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qd	Not Reported
	Imuran /00001501/	C	Unknown		Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	50 Mg, Bid	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported

Furosemid /00032602/	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C			Not Reported
Lyrica	C	Unknown	75 Mg, Qd	Not Reported
Naproxen	C	Unknown	500 Mg, Qd	Not Reported
Nifedipine	C	Unknown	Unk	Not Reported
Palafer	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, Bid	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Toloxin /00017701/	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	50 Mg, Qd	Not Reported
Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Zinc Citrate	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	C	Unknown	200 Mg, Q.O.Wk.	Not Reported
Azathioprine	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Oral	500 Milligram, Bid	Not Reported
Dorzolamide Hydrochloride;Timolol Maleate	C	Unknown	2 Dosage Form, Qd	Not Reported
Estradiol	C	Unknown	Unk	Not Reported
Estrogel	C	Unknown	1 Dosage Form, Qd	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
Xalatan	C	Unknown	50 Microgram, Qd	Not Reported
Zingiber Officinale	C	Unknown	500 Milligram	Not Reported

Vitamin D [Colecalciferol]	C	Unknown	Unk		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	50 Milligram, Bid		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	14235033	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP021680		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	200 Mol, Bid		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.,731.0		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Once Every 6 Weeks		Not Reported
	Remicade			S	Unknown	300 Mg, Once Every 6 Weeks		Not Reported

Rituxan	S	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Wellbutrin	C	Unknown			Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported
Bupropion	C	Unknown	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Simponi	C	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Milligram, Bid		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	14238407	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP021637		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Back Pain; Bone Density Abnormal; Contraindicated Product Administered; Crying; Decreased Appetite; Depression; Disability; Drug Ineffective; Fatigue; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Loss Of Personal Independence In Daily Activities; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Milligram, Qd		Apotex
	Indomethacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	25 Mg, Qd		Apotex
	Prednisone			S	Oral	3 Mg, Qd		Apotex
	Prednisone			S	Oral	50 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Prednisone			S	Oral	3 Mg, Qd		Apotex
	Apo-Prednisone			S	Oral	50 Mg, Qd		Apotex
	Apo-Prednisone			S	Oral	25 Milligram, Qd		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported

Mass; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure; Unevaluable Event; Vomiting	Methotrexate Sodium	S	Oral	25 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Indocid /00003801/	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	30 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cymbalta	C	Oral	30 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Folic Acid	C	Oral	Unk, Q.Wk.	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	14740528	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP009465		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Naprosyn /00256201/			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	14746072	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

				otherwise specified)			
	Plaquenil Sulfate		S	Unknown	Unk		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Xeljanz		C	Oral	5 Milligram		Not Reported
	Prednisone		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	14752376	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009509			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	14797823	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1232		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis Noninfective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	400 Mg, Cyclic (6 Times/Wk)		Not Reported
	Hydroxychloroquine			C	Unknown	400 Mg, Cyclic		Not Reported
	Celebrex			C	Unknown			Not Reported
	L-Thyroxine			C	Unknown			Not Reported
	Tylenol Arthritis			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	17729486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During	Diclofenac Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Calcium Gluconate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Quetiapine	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	17827314	EXPEDITED (15-DAY)		OT	BN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247483		60 YR	Female	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	17830313	EXPEDITED (15-DAY)		OT	FR-009507513-2005FRA006026		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Celestene Chronodose			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd (5,70 Mg/Ml, Suspension Injectable)		Merck

	Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 Gram, Qd	Not Reported
	Zithromax	S	Oral	250 Milligram, Qd	Not Reported
	Plaquenil	S	Oral	600 Milligram, Qd	Not Reported
	Lovenox	C		Mammal/Pork/Intestinal Mucosa	Not Reported
	Potassium Acetate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	17954143	EXPEDITED (15-DAY)		OT	CA-ACCORD-187234		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Methotrexate			S	Subcutaneous			Accord
	Mycophenolic Acid			S	Unknown			Accord
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Aurothioglucose			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Penicillamine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution, 1 Every 1 Months		Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Elavil			C				Not Reported

	Prednisone		C	Unknown		Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Tobramycin		C	Unknown		Not Reported
	Xeljanz		C	Oral	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18032030	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020271020			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Oral	5 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18212456	EXPEDITED (15-DAY)		OT	CA-ACCORD-198264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered;	Methotrexate			S	Unknown	1 Every 1 Weeks, Not Specified		Accord
	Arava			S	Unknown	1 Every 1 Days		Not Reported

Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Every 1 Days	Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days, Not Specified	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Prednisone	S	Unknown	1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18212789	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2020M1075163			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Ocular Icterus; Pruritus; Yellow Skin	Azithromycin			S		500 Milligram (500 Mg Per Day)		Mylan
	Zink /00156501/			S		120 Milligram(120 Mg Per Day)		Mylan
	Hydroxychloroquine			S		400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18224640	EXPEDITED (15-DAY)		OT	CA-ACCORD-198727		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling;	Methotrexate			S		Frequency: 1 Every 1 Weeks		Not Reported

Pulmonary Mass	Hydroxychloroquine	S	Frequency:1 Every 1 Days	Not Reported
	Kevzara	S		Not Reported
	Sulfasalazine	S	Frequency:3 Every 1 Days	Not Reported
	Atorvastatin	C		Not Reported
	Candesartan	C		Not Reported
	Ergocalciferol	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18224648	EXPEDITED (15-DAY)		OT	CA-ACCORD-198731		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Alendronate Sodium/Alendronic Acid			S				Accord
	Methotrexate			S	Oral			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Pre-Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	Frequency: 1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	Frequency: 1 Every 1 Days	Not Reported
	Topicort	S	Cutaneous		Not Reported
	Xeljanz	C			Not Reported
	Leflunomide	C			Not Reported
	Hydroxychloroquine	S	Oral	Frequency: 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18224689	EXPEDITED (15-DAY)		HO	IT-LAURUS LABS LIMITED-202000171			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urinary Tract Infection	Hydroxychloroquine			S	Oral			Unknown
	Darunavir/Ritonavir			S	Unknown	800/100		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18224970	EXPEDITED (15-DAY)		HO, LT, OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05367		50 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Off Label Use; Respiratory Distress	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Methylprednisolone			S	Unknown	16 Milligram, Qd		Lupin
	Methylprednisolone			S	Unknown	1 Milligram/Kilogram, Qd (80 Mg)		Lupin
	Everolimus			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225011	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05368		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225069	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05370		80 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Decreasing)		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225256	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820614		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225257	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820289		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225261	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05371		60 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Decreased)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225328	NON-EXPEDITED		OT	CH-LUPIN PHARMACEUTICALS INC.-2020-03509			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous	Hydroxychloroquine			S	Unknown	Unk		Lupin

Pustulosis; Rash Maculo-Papular	Budesonide		S	Unknown	Unk	Lupin
	Aspirine		C	Unknown	Unk	Not Reported
	Levetiracetam		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225333	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-05183		60 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Loading Dose (2 Days)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Maintenance Dose		Lupin
	Oseltamivir			S	Unknown	75 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	500 Milligram, Loading (1st Day)		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd		Lupin
	Sodium Bicarbonate			C	Unknown	Unk		Not Reported
	Favipiravir			C	Unknown	1600 Milligram, Loading, First Day 2		Not Reported
	Favipiravir			C	Unknown	600 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225376	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Prednisone	S	Intravenous (not otherwise specified)	3 Milligram Daily;		Not Reported
Prednisone	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225385	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-05185		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225421	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05372		60 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported

	Mycophenolate		C	Unknown	Unk	Not Reported
	Mycophenolate		C	Unknown	1 Gram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225445	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05194		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225495	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-045849			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lividity; Off Label Use; Rash	Azithromycin			S	Unknown	Unk		Aurobindo
	Furosemide			S	Unknown	Unk		Aurobindo
	Meropenem			S	Unknown	Unk		Aurobindo
	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225497	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05373		50 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Everolimus			C	Unknown	Unk		Not Reported
	Everolimus			C	Unknown	Unk (Dose Decreasing)		Not Reported

	Mycophenolate		C	Unknown	1 Gram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225532	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05374		50 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Ciclosporin			C	Unknown	Unk		Not Reported
	Ciclosporin			C	Unknown	Unk (Dose Decreasing)		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225540	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05377		60 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid- (On Day 1) For 5 Days		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Dose Decreasing)		Not Reported
	Azathioprine			C	Unknown	1 Millilitre Per Kilogram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225564	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05376		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin

Tacrolimus	C	Unknown	Unk		Not Reported
Tacrolimus	C	Unknown	Unk (Dose Decreasing)		Not Reported
Mycophenolate	C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225582	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1820699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225802	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-27145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Product Use In Unapproved Indication	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Oral			Not Reported
	Bisoprolol			S	Unknown	Unknown		Not Reported

Cefixime	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Morphine	S	Unknown	Unknown		Not Reported
Nifedipine	S	Unknown	Unknown		Not Reported
Pantoprazole	S	Unknown	Unknown		Not Reported
Prednisone	S	Unknown	Unknown		Not Reported
Rivotril	S	Unknown	Unknown		Not Reported
Zantac	S	Unknown	Unknown		Not Reported
Zopiclone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226239	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05378		70 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Ciclosporin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226260	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05379		60 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Methylprednisolone			S	Unknown	32 Milligram, Qd		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Dose Decreasing)		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226281	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05380		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Dose Decreasing)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226301	EXPEDITED (15-DAY)		HO, OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05381		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Dose Decreased)		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226323	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05382		70 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Everolimus			C	Unknown	Unk		Not Reported
	Everolimus			C	Unknown	Unk (Dose Decreasing)		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226336	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-05383		60 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid-On Day 1		Lupin
	Tacrolimus			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk (Dose Decreased)		Not Reported
	Mycophenolate			C	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226869	EXPEDITED (15-DAY)		OT	CA-ACCORD-198636		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226877	EXPEDITED (15-DAY)		OT	CA-ACCORD-198723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			S	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226958	EXPEDITED (15-DAY)		OT	CA-ACCORD-198695		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Methotrexate			S				Accord
	Mycophenolic Acid			S				Accord
	Tacrolimus			S				Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226971	EXPEDITED (15-DAY)		OT	CA-ACCORD-198724		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported

	Anakinra	S	Subcutaneous	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Intramuscular	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226972	EXPEDITED (15-DAY)		OT	CA-ACCORD-198725		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Methotrexate			S	Subcutaneous			Not Reported
	Azathioprine			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Not Reported
	Apo-Azathioprine			S				Not Reported
	Humira			S	Subcutaneous	Frequency: 1 Every 2 Weeks, Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S	Subcutaneous	Frequency: 1 Every 1		Not Reported

				Weeks	
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	C			Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18227055	NON-EXPEDITED			US-PFIZER INC-2020336915			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Byetta			S		Unk		Not Reported
	Januvia [Sitagliptin Phosphate]			S		Unk		Not Reported
	Levemir			S		Unk		Not Reported
	Propoxyphene And Acetaminophen			S		Unk		Not Reported
	Ceftin [Ceftriaxone]			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18227871	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335549			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg (The First Day)		Pfizer
	Azithromycin			S		250 Mg (Subsequent Days		Pfizer

						)				
	Hydroxychloroquine			S		200 Mg, 3x/Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18227916	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335320		84 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg For The First Day		Pfizer
	Azithromycin			S		250 Mg For The Subsequent 4 Days		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18227918	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2020335547			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Azithromycin			S		500 Mg (First Day)		Pfizer
	Azithromycin			S		250 Mg (The Subsequent Days)		Pfizer
	Hydroxychloroquine			S		200 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228347	EXPEDITED (15-DAY)		OT	NVSC2020CA239300		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228620	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016899		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Bone Marrow Toxicity; C-Reactive Protein Increased; Intentional Product Use Issue; Neuropathy Peripheral; Off Label Use; Paraesthesia; Rash; Thrombocytopenia	Leflunomide			S	Unknown	10 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Q.Wk.		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	680 Milligram, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228712	EXPEDITED (15-DAY)		HO	US-VALIDUS PHARMACEUTICALS LLC-US-2020VAL000710			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Off Label Use	Furosemide			S	Unknown	Unk		Validus
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Piperacillin W/Tazobactam /01606301/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228769	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016921		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228963	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05431		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Kaletra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229184	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05213		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Dexamethasone			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229185	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05428		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S	Unknown	Unk		Lupin
	Amoxicillin + Clavulanic Acid	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229187	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05211			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229192	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05219			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229193	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05215			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229194	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS		39 YR	Female	USA

INC.-2020-05214

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229196	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05430		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229202	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05216		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229203	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05429		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Kaletra			S	Unknown	Unk		Not Reported

	Tocilizumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229205	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05221		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229413	EXPEDITED (15-DAY)		OT	US-AMERICAN REGENT INC-2020001777		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Disorder	Furosemide Injection, Usp (5702-25)			S	Unknown	Unk		American Regent
	Meropenem			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Piperacilline/Tazobactam			S	Unknown	Unk		Not Reported
	Heparin /00027704/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229445	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1076219		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram		Mylan
	Acetylcysteine			S	Intravenous (not otherwise specified)	30000 Milligram, Three Times/24 Hours		Unknown

	Acetylcysteine		S	Intravenous (not otherwise specified)	600 Milligram, Bid For 1 Week	Unknown
	Acetylcysteine		S	Intravenous (not otherwise specified)	600 Milligram, Bid	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229576	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1076241		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjacent Segment Degeneration	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Prednisone			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229667	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-27188		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability;	Etanercept			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported
	Leflunomide		S	Oral	Unknown	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Unknown	Unknown	Not Reported
	Orencia		S			Not Reported
	Rituximab		S	Unknown		Not Reported
	Rituximab		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229684	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2020-AMRX-01557			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Fatigue; Therapy Cessation	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2 /Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18230489	EXPEDITED (15-DAY)		DE, LT, OT	CH-ABBVIE-20K-151-3551604-00		81 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Electrocardiogram Qt Prolonged; Hyperkalaemia; Hypokalaemia; Hyponatraemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18276455	DIRECT					50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Use In Unapproved Indication	Hydroxychloroquine		S	Oral	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18276728	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Oseltamivir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Lopinavir-Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18276732	DIRECT		DE			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Haemodialysis; Off Label Use	Lopinavir-Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Dexamethasone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18276785	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18276841	DIRECT		DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue;	Lopinavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Ritonavir			S				Not Reported

Respiratory Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18276928	DIRECT					40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S				Not Reported
	Oseltamivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18277069	DIRECT					70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue; Urinary Tract Infection Enterococcal	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18277312	DIRECT					70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Death; Haemodialysis; Product Use Issue	Lopinavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Dexamethasone			S				Not Reported
	Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18277494	DIRECT					30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Product Use In Unapproved Indication;	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported

Product Use Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	12891950	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-APOPHARMA INC-2016AP013468			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S				Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Unknown	Unk Unk, Unknown		Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Remicade	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab	S				Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S				Not Reported
	Ilaris	S	Subcutaneous	Unk		Not Reported
	Ilaris	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	12893024	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013313		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Naproxen			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Naproxen Sodium			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	14751157	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009666			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Milligram		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	14778860	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported

	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Unk		Not Reported
	Otezla	S	Oral	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	15076484	EXPEDITED (15-DAY)		LT, OT	CA-APOTEX-2018AP015974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk 1 Every 10 Days		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk 1 Every 10 Days		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg, One Every Four Weeks		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, One Every Four		Not Reported

				Weeks		
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Tofacitinib	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Kevzara	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Sarilumab	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	20 Mg, Unk		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	15090030	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016084		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

	Loperamide	C	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported
	Actemra	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	16543922	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017643		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Rosuvastatin			S	Unknown	Unk		Apotex
	Rosuvastatin			S	Oral	5 Milligram, Bid		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Cephalexin /00145501/			C	Unknown	500 Mg, Qid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	17242377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018036		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cephalexin [Cefalexin]			C	Unknown	500 Milligram, Qid		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Coversyl /00790702/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	17449110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea;	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Sinusitis; Urosepsis	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Certolizumab Pegol	S	Unknown	400 Milligram, Q.O.Wk.	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Intratumor	8 Milligram/Kilogram	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Certolizumab Pegol	C	Unknown	400 Mg, Q.O.Wk.	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Tocilizumab	C	Unknown	8.0 Mg/Kg, (One Evey Four Weeks)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	17449223	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007791		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	40 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported

Methotrexate	S	Subcutaneous	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Tofacitinib	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Kevzara	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Prednisone	C	Unknown	10 Mg, Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported
Cimzia	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	17857621	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2020AP011340		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abscess; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatic Fibrosis; Infection; Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis; Sepsis; Spinal Cord Infection; Therapeutic Product Effect Decreased	Azathioprine			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	100 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Prednisone			S	Oral	12.5 Milligram, Qd		Not Reported
	Prednisone			S	Oral	Unk, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Actemra	S	Unknown	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Mobicox	S	Unknown	15 Mg, Qd	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Vioxx	S	Unknown	25 Mg, Qd	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Methotrexate	S	Intramuscular	Unk Unk, Q.Wk.	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Methotrexate	C	Intramuscular	Unk, Q.Wk.	Not Reported
Plaquenil /00072602/	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	12.5 Mg, Qd	Not Reported
Azathioprine	C	Unknown	Unk Unk, Qd	Not Reported
Humira	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	200 Milligram, Bid	Not Reported
Mobicox	C	Unknown	15 Milligram, Qd	Not Reported
Myochrysine	C	Intramuscular	50 Milligram, Q.M.T.	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Vioxx	C	Unknown	25 Milligram, Qd	Not Reported
Voltaren [Diclofenac]	C	Unknown	100 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	17942970	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012568		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased;	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Methotrexate	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Apotex
	Actemra	S	Intravenous (not otherwise specified)	680 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	380 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	624 Mg, 1 Every 4 Weeks	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	624 Mg, 1 Every 4 Weeks	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	680 Mg, 1 Every 4 Weeks	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Lasix [Furosemide]	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Oxycontin	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	17966443	EXPEDITED (15-DAY)		OT	CI-ADVANZ PHARMA-202006006795			Unknown	CIV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18040728	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020IT200469		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Creatinine Increased; Covid-19 Pneumonia; Drug Interaction; Drug Trough Level; Labelled Drug-Food Interaction Medication Error; Nausea; Product Use In Unapproved Indication; Vomiting	Tacrolimus			S	Unknown	5 Mg, Bid		Novartis
	Tacrolimus			S	Unknown	3 Mg, Bid		Novartis
	Lopinavir,Ritonavir			S	Unknown	400/100 Mg, Bid		Not Reported
	Lopinavir,Ritonavir			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Ceftriaxone			S	Unknown	2 Mg, Qd		Not Reported
	Cobicistat			S	Unknown			Not Reported
	Methylprednisolone			C	Unknown	4 Mg, Qd		Not Reported
	Methylprednisolone			C	Unknown	6.5 Mg, Qd		Not Reported
	Methylprednisolone			C				Not Reported
	Omeprazole			C	Unknown	20 Mg, Qd		Not Reported
	Allopurinol			C	Unknown	150 Mg, Qd		Not Reported
	Atorvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Ramipril			C	Unknown	2.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18229909	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260032		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypertransaminasaemia	Azithromycin	S	Unknown	500 Milligram, Daily	Sun
	Hidroxicloroquina (2143a)	S	Unknown	200 Milligram/ 2days	Not Reported
	Lopinavir+Ritonavir	S	Unknown	2 Cp / 12 Horas ()	Not Reported
	Polaramine	C	Unknown	6 Milligram/ 3 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18230244	EXPEDITED (15-DAY)		OT	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-055086			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cardiomegaly; End Stage Renal Disease; Maculopathy; Prescribed Overdose; Retinopathy	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Zydus Pharm
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (200 Mg Twice Daily, 8.2 Mg/Kg Actual Body Weight Per Day)		Zydus Pharm
	Prednisone			C		Unk		Not Reported
	Prednisone			C		Unk (Increased)		Not Reported
	Mycophenolate			C		Unk		Not Reported
	Mycophenolate			C		Unk (Increased)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18230398	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1821616			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Morphine			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cannabis Sativa			C				Not Reported

	Dronabinol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18230613	EXPEDITED (15-DAY)		OT	IL-LUPIN PHARMACEUTICALS INC.-2020-05184		61 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pancreatitis Acute	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	800 Milligram, Qd (Loading Dose Of 800 Mg On Day 1)		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Lupin
	Ciprofloxacin			S	Intravenous (not otherwise specified)	400 Milligram, Bid		Lupin
	Acetaminophen			S	Unknown	1000 Milligram, Prn (On 4 Different Occasions)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	10 Milligram, Bid (5 Days With Tapering Thereafter)		Not Reported
	Pantoprazole			S	Intravenous (not otherwise specified)	40 Milligram, Qd		Not Reported
	Zinc			C	Unknown	50 Milligram, Bid		Not Reported
	Clindamycin			C	Oral	300 Milligram, Qid		Not Reported
	Enoxaparin			C	Unknown	80 Milligram, Bid		Not Reported
	Lopinavir/Ritonavir			C	Unknown	2 Dosage Form, Bid (2 Tablets Of 200 Mg/50 Mg Twice Daily For 5 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18230781	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05539		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Methylprednisolone	S	Unknown	4 Milligram, Qd	Lupin
	Methylprednisolone	S	Unknown	6.5 Milligram, Qd	Lupin
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Lupin
	Ceftriaxone	S	Unknown	2 Gram, Qd	Lupin
	Tacrolimus	C	Unknown	5 Milligram, Bid	Not Reported
	Tacrolimus	C	Unknown	3 Milligram	Not Reported
	Lopinavir/Ritonavir	C	Unknown	1 Dosage Form, Bid	Not Reported
	Lopinavir/Ritonavir	C			Not Reported
	Cobicistat;Darunavir	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	20 Milligram, Qd (Stopped On: 06-Mar-2020)	Not Reported
	Allopurinol	C	Unknown	150 Milligram, Qd	Not Reported
	Omeprazole	C	Unknown	20 Milligram, Qd	Not Reported
	Ramipril	C	Unknown	2.5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18230995	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202008008359			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Exposure During Pregnancy; Premature Rupture Of Membranes	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Predonine			C		15 Mg, Qd		Not Reported
	Predonine			C		Unk		Not Reported
	Bufferin 500			C		Unk		Not Reported
	Bufferin 500			C				Not Reported
	Prednisolone			C		Unk		Not Reported
	Prograf			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231053	EXPEDITED (15-DAY)		DE, OT	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-055467			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Nephropathy Toxic	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (4.2 Mg Per Kg)		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231098	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2020-05406			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Paracetamol			C	Unknown	Unk		Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231187	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202008008361			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Hepatic Enzyme Increased; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Prednisone			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231542	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-068626		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia	Coumadine			S	Oral	Unk		Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231706	EXPEDITED (15-DAY)		HO	CN-SGP-000090		72 YR	Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Disease Progression; Product Use In Unapproved Indication	Methylprednisolone			S	Oral	40 Mg Po Qd		Sungen Pharma
	Methylprednisolone			S	Unknown	4 Mg/Day		Sungen Pharma
	Methylprednisolone			S	Unknown	16 Mg/Day		Sungen Pharma
	Methylprednisolone			S	Unknown	Dosage Of Glucocorticoid Was Increased		Sungen Pharma
	Oseltamivir Phosphate			S	Unknown			Not Reported
	Lopinavir,Ritonavir			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Mg Po Qd		Not Reported
	Hydroxychloroquine			S	Oral	0.2 G Po Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231708	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1821973		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Linezolide			S	Intravenous drip	Unspecified		Teva
	Azithromycine			S	Oral	Unspecified		Not Reported
	Tienam			S	Intravenous drip	Unspecified		Not Reported
	Plaquenil			S	Oral	Unspecified		Not Reported

	Tazocilline	S	Intravenous drip	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231812	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05432		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd- Per Week		Not Reported
	Prednisone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd- Per Week		Not Reported
	Prednisone			C	Unknown	40 Milligram, Qd		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231891	EXPEDITED (15-DAY)		HO	IN-MYLANLABS-2020M1076027		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Face Oedema; Lymphadenopathy; Oedema Peripheral	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Sulfasalazine			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231912	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017013			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex

	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Januvia [Sitagliptin Phosphate]			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18231968	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020340968		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Lidocaine Hcl			S	Topical	Unk		Pfizer
	Lidocaine Hcl			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Amitriptyline			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown			Not Reported
	Bumetanide			S	Unknown			Not Reported
	Capsaicin			S	Topical	Unk		Not Reported
	Cimetidine			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Diltiazem			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibudilast			S	Unknown			Not Reported
	Ketamine			S	Oral	Unk		Not Reported
	Ketamine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ketamine			S	Topical	Unk		Not Reported
	Lithium Carbonate			S	Unknown			Not Reported

Magnesium	S	Unknown		Not Reported
Memantine	S	Unknown		Not Reported
Metprolol	S	Unknown		Not Reported
Mexiletine	S	Unknown		Not Reported
Montelukast	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
N-Acetylcysteine	S	Unknown		Not Reported
Naltrexone Hydrochloride	S	Unknown	4.5 Mg, 1x/Day (Frequency: 1 Every 24 Hours)	Not Reported
Palmitoylethanolamide	S	Unknown		Not Reported
Pentoxifylline	S	Unknown		Not Reported
Prednisone	S	Unknown	Unk, 1x/Day (Frequency: 1 Every 24 Hours)	Not Reported
Prednisone	S	Unknown	95 Mg, Daily (Frequency: 1 Every 24 Hours)	Not Reported
Prednisone	S	Unknown	5 Mg	Not Reported
Prednisone	S	Unknown	Unk, 1x/Day (1 Every 24 Hours)	Not Reported
Prednisone	S	Unknown	13 Mg	Not Reported
Prednisone	S	Unknown	85 Mg, 1x/Day (1 Every 24 Hours)	Not Reported
Pregabalin	S	Unknown		Not Reported
Spironolactone	S	Unknown		Not Reported
Vitamin B 2	S	Unknown		Not Reported
Vitamin B 2	S			Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown		Not Reported
Trazodone	C	Unknown		Not Reported
Ezetimibe	C	Unknown		Not Reported
Calcitonin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232827	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1075706		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Lopinavir/Ritonavir			S		800 Milligram, Qd		Mylan
	Plaquenil /00072603/			S		600 Milligram, Qd		Mylan
	Rezolsta			C		800 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232835	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1075671		68 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Lopinavir/Ritonavir			S		800 Milligram, Qd		Mylan
	Plaquenil /00072603/			S		400 Milligram, Qd		Mylan
	Levomepromazine			C		100 Milligram, Qd		Mylan
	Zuclopenthixol			C		Unk		Mylan
	Haloperidol			C		20 Gtt Drops, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232838	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1075689		82 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Lopinavir/Ritonavir			S		800 Milligram, Qd		Mylan
	Plaquenil /00072603/			S		400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232840	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1075676		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Off Label Use	Lopinavir/Ritonavir	S	400 Milligram, Qd	Mylan
	Plaquenil /00072603/	S	400 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232852	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1822327			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233523	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1076672		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid On Day 1		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid On Days 2-5		Mylan
	Azithromycin			S	Unknown	500 Milligram On Day 1		Mylan

Azithromycin	S	Unknown	250 Milligram On Days 2-5		Mylan
Bivalirudin	S	Unknown	03-0.4 Microg/Kg/H		Mylan
Methylprednisolone	S	Unknown	40 Milligram, Bid On Days 1-3		Mylan
Anakinra	S	Unknown	100 Milligram, Q6h On Days 1-5		Mylan
Anakinra	S	Unknown	100 Milligram Every 12 Hours On Days 5-10		Mylan
Anakinra	S	Unknown	100 Milligram, Qd On Days 11-13		Mylan
Remdesivir	S	Unknown	200 Milligram On Day 1		Mylan
Remdesivir	S	Unknown	100 Milligram, Qd Days 2-5		Mylan
Nitric Oxide	S	Unknown	Unk		Mylan
Thrombate Iii	S	Unknown	Unk		Mylan
Epinephrine	C		Unk		Mylan
Vancomycin	C	Unknown	Unk		Mylan
Cefepime	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233588	EXPEDITED (15-DAY)		HO, LT, OT	US-SA-2020SA229618			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Encephalopathy; Fall; Hypercapnia; Hypoxia; Lung Opacity; Muscle Injury; Muscular Weakness; Myopathy Toxic; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Subarachnoid	Hydroxychloroquine Sulfate			S		200 Mg, Bid, Prolonged Hiatus		Sanofi
	Hydrocortisone Salt Not Specified		Y	S		30 Mg, Qd (20 Mg In The Morning And 10 Mg In Afternoon)		Sanofi
	Corticosteroid Nos			S				Not Reported
	Anakinra			C	Subcutaneous	100 Mg, Qd		Not Reported

Haemorrhage; Tibia Fracture; Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233978	EXPEDITED (15-DAY)		OT	SE-TEVA-2020-SE-1822643			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Ocular Icterus; Pruritus; Yellow Skin	Azitromycin			S		500 Milligram Daily;		Not Reported
	Zink			S		120 Milligram Daily;		Not Reported
	Hydroxychloroquine			S		400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18234076	EXPEDITED (15-DAY)		OT	CA-SA-2020SA233410			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Treatment Failure	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18234207	EXPEDITED (15-DAY)		OT	KR-ABBVIE-20K-090-3549264-00		78 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Kaletra 200/50			S	Oral	Lopinavir 200 Mg/Ritonavir 50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ceftriaxone			C				Not Reported
	Levofloxacin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Meropenem			C				Not Reported
	Vancomycin			C				Not Reported
	Paracetamol			C				Not Reported
	Peramivir			C				Not Reported

	Methylprednisolone	C	Not Reported
	Methylprednisolone	C	Not Reported
	Teicoplanin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18234609	EXPEDITED (15-DAY)		OT	NVSC2020TR237264		65 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Favipiravir			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18234668	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3552509-00		60 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Diarrhoea; Nausea; Off Label Use	Kaletra			S	Oral	500mg 12/12h		Not Reported
	Plaquinol			S	Oral	200 Mg 24/24h		Not Reported
	Enoxaparin Sodium			C				Not Reported
	Co-Trimoxazole			C				Not Reported
	Prednisolone			C				Not Reported
	Paracetamol			C				Not Reported
	Amlodipine			C				Not Reported
	Omeprazole			C				Not Reported
	Bromazepam			C				Not Reported
	Mycophenolic Acid			C				Not Reported
	Insulin Human Isophane			C	Subcutaneous			Not Reported
	Insulin Human			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18276646	DIRECT		DE			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine	S		Not Reported
	Azithromycin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18276737	DIRECT		DE			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cough; Fatigue; Myalgia; Off Label Use	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18276975	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Death; Disease Progression; Haemodialysis; Product Use In Unapproved Indication; Product Use Issue	Lopinavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Dexamethasone			S				Not Reported
	Tocilizumab			S				Not Reported
	Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18276981	DIRECT		DE			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Complications Of Transplanted Kidney; Product Use In Unapproved Indication; Product Use Issue	Lopinavir-Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Dexamethasone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18277904	DIRECT		DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Disease Progression; Dyspnoea; General Physical Health Deterioration; Haemodialysis; Off Label Use; Pyrexia	Lopinavir			S				Not Reported
	Dexamethasone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18278072	DIRECT					50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lopinavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Dexamethasone			S				Not Reported
	Ritonavir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	13676502	EXPEDITED (15-DAY)		OT	CA-TEVA-780631ACC		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder;	Actonel			S	Unknown			Teva
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Risedronic Sodium			S	Unknown			Teva

Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronic Sodium	S	Oral		Teva
	Risedronic Sodium	S	Unknown		Teva
	Risedronic Sodium	S	Oral		Teva
	Actemra	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Vaginal		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Forms Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1200 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	7200 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram Daily;		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Apo-Leflunomide	S	Oral	20 Milligram Daily;		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Apo-Leflunomide	S	Oral	480 Milligram Daily;		Not Reported
Apo-Risedronate	S	Unknown			Not Reported
Anakinra	S	Subcutaneous			Not Reported
Anakinra	S	Subcutaneous			Not Reported
Anakinra	S	Oral			Not Reported
Arava	S	Oral			Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
Gold	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Hydroxychloroquine	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	13967555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017891		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex

Apo-Leflunomide	S	Unknown	20 Mg, Unk		Apotex
Actemra	S	Unknown	8 Mg, Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Gold	S	Unknown	50 Mg, Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
Orencia	S	Unknown	750 Mg, Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	17260297	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	420 Milligram, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Dorzolamide ,Timolol			S	Unknown	1 Df, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk Unk, Bid		Apotex
	Ramipril			S	Oral	Unk, Qd		Apotex
	Ramipril			S	Oral	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Levothyroxine			S	Unknown	1 Df, Unk		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Endocervical	400 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Unknown	25 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Dorzolamide Hydrochloride W/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported
Folic Acid	C	Unknown		Not Reported
Levothyroxine	C	Unknown	Unk Unk, Qd	Not Reported
Prednisone	C	Unknown	7 Mg, Qd	Not Reported
Ramipril	C	Unknown	One Once A Day	Not Reported
Tylenol No.2	C	Unknown		Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Caffeine	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Meprobamate	C	Unknown	Unk	Not Reported
Timolol Maleate	C	Ophthalmic	Unk Unk, Bid	Not Reported
Dorzolamide Hydrochloride	C	Ophthalmic	Unk Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18036637	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-253382		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	Unk		Sun
	Dobutamine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18100439	EXPEDITED (15-DAY)			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255169			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Hydroxychloroquine			S	Transplacental	Unk		Sun
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18201087	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-197432		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S				Not Reported
	Anakinra			C	Subcutaneous			Not Reported
	Hydrocortisone			C		20 Mg Every Morning And 10 Mg In The Afternoon		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18226483	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-259944		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Off Label Use; Tachyarrhythmia; Tachycardia; Vomiting; Weight Decreased	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Plaquenil			S	Oral	200 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235193	EXPEDITED (15-DAY)		OT	MA-LUPIN PHARMACEUTICALS INC.-2020-05217		69 YR	Male	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Tid		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Ceftriaxone			S	Unknown	2 Gram, Qd		Lupin
	Moxifloxacin Hydrochloride			S	Unknown	400 Milligram, Bid		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235361	EXPEDITED (15-DAY)		OT	QA-LUPIN PHARMACEUTICALS INC.-2020-05435		28 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235417	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05392		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Propofol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235624	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1823052		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate	S	Unknown			Barr
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	3 Milligram Daily;		Not Reported
	Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235656	EXPEDITED (15-DAY)		OT	CA-ACCORD-199508		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S				Accord
	Rituximab			S				Not Reported
	Remicade			S				Not Reported
	Orencia			S				Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S		1 Every 24 Hours		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Leflunomide			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235675	EXPEDITED (15-DAY)		OT	ES-ACCORD-199247		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Nausea; Off Label Use	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Kaletra			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235709	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1823789		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Methotrexate			S	Unknown			Barr
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235853	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1823821		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown	700 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram Daily;		Not Reported
	Atorvastatin Calcium			C				Not Reported
	Candesartan			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1823965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular	12.5 Milligram Daily;		Barr
	Arava			S	Oral			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235873	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1823819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis;	Methotrexate			S	Other			Barr
	Enbrel			S	Unknown			Not Reported

Stomatitis; Swelling	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18235875	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1823977		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	16079887	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05894		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy;	Infliximab			S	Unknown	Unknown		Not Reported

Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unknown. Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Methotrexate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18038401	NON-EXPEDITED		OT	IT-AMGEN-ITASP2020116255			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Oral	5 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18236134	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2020-CA-1824020			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Erythematosus; Wheelchair User	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18236137	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824018		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18236140	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1824016		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18236242	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Piroxicam	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18281256	DIRECT					70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S			1 DAY	Not Reported
	Hydroxychloroquine			S	Oral		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18281262	DIRECT					51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S			1 DAY	Not Reported
	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	12782794	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP012086		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Mycophenolate			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	7 Mg, Qd		Not Reported
	Prednisone			C				Not Reported

Humira	C	Subcutaneous	Unk		Not Reported
Humira	C				Not Reported
Methotrexate	C	Unknown	1 Ml, Q.Wk.		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Humira	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	12883751	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Q.12h		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	13054285	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Leflunomide			S	Oral	10 Mg, Qd		Apotex

Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine	S	Oral	200 Mg, Unk	Apotex
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Apotex
	Actemra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	20 Milligram, Q.O.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Actemra	C	Subcutaneous	Unk	Not Reported
	Enbrel	C	Subcutaneous	Unk	Not Reported
	Humira	C	Unknown	40 Mg, Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Orencia	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Unknown	Unk	Not Reported

	Xeljanz		C	Unknown	Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported
	Wellbutrin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	13068783	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161203380		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Incorrect Dose Administered; Joint Warmth; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Tremor	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Enbrel			S	Subcutaneous	Duration Is 9 Months		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous	Cyclical For -244.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Morphine /00036302/			S	Topical	1.0 Dosage Form		Not Reported
	Naprosyn /00256201/			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Zopiclone			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Pantoprazole Magnesium			C	Oral			Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral			Not Reported

	Xeljanz	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported
	Rituximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	13251590	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006777		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	10 Milligram		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Prednisone			C	Oral	5 Mg, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

Prednisone	C	Oral	50 Milligram, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	13958227	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017824		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	Unk, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral	Unk, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	14744581	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Desoximetasone	C	Unknown	10 Mg, Qd		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported
Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	15509701	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016273080		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Covid-19; Dehydration; Dysphagia; Dyspnoea; Fatigue; Gastrooesophageal Reflux Disease; Glaucoma; Pharyngeal Swelling; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (Crushed Up)		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Plaquenil			S		200 Mg, 1x/Day		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Atorvastatin			C		20 Mg, Unk		Not Reported
	Latanoprost			C		Unk, ([125mg/2.5ml])		Not Reported
	Stiolto Respimat			C		Unk		Not Reported
	Claritin [Loratadine]			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	15741775	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20181216635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased;	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	16456054	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016547		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Ciprofloxacin			S	Unknown	Unk		Apotex
	Enalapril			S	Unknown	Unk		Apotex
	Clindamycin			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Hydralazine			S	Unknown	Unk		Apotex

Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Losartan	S	Unknown	Unk	Apotex
	Moxifloxacin	S	Unknown	Unk	Apotex
	Metoprolol	S	Unknown	Unk	Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Cephalexin	S	Unknown	Unk	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Keflex /00145501/	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G /00000901/	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Mg, Bid	Not Reported
	Tecta	S	Unknown	Unk	Not Reported
	Moxifloxacin Sandoz	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Lopressor	S	Unknown	Unk	Not Reported
	Cipro /00697201/	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported

	Prednisone	C	Unknown	8.5 Mg, Qd, 1 Every 1 Day	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Atenol	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Leucovorin /00566701/	C	Unknown	Unk	Not Reported
	Ranitidine	C	Unknown	Unk	Not Reported
	Colchicine	C	Unknown	Unk	Not Reported
	Coversyl /00790702/	C	Unknown	Unk	Not Reported
	Veltassa	C	Unknown	Unk	Not Reported
	Venofer	C	Unknown	Unk	Not Reported
	Levothyroxine	C	Unknown	Unk	Not Reported
	Atenolol Bp	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17566305	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Enbrel	S	Unknown	Duration- 730 And 731 (Unspecified Units)	Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Cimzia	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Imuran /00001501/	C	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Arthrotec	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17611318	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160614521		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Ndc: 412545		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17623404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342106		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17623466	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340460		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17623540	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200340132			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Hypersensitivity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid	Simponi			S	Subcutaneous			Not Reported
	Diphenhydramine Hydrochloride		Y	S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure			otherwise specified)	
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Benzalkonium Chloride	S	Unknown	Not Reported
	Benzalkonium Chloride W/Diphenhydra/03049201/	S	Unknown	Not Reported
	Boric Acid	S	Unknown	Not Reported
	Disodium Edetate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Phenylephrine Hydrochloride	S	Unknown	Not Reported
	Rho D Immune Globulin	S	Unknown	Not Reported
	Sodium Borate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17623542	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200340452		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17666251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009862		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Intravenous (not otherwise specified)	Unk		Apotex
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported

	Humira	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
	Neoral	S	Subcutaneous	125 Milligram	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz Xr	C	Unknown	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17672254	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17712397	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200432625		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Off Label Use	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	17932928	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP019645		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Cannabis Sativa	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unk		Not Reported
Oxycodone	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	7 Mg, Qd		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18142450	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP015355		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect	Naproxen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	616 Milligram Cyclical		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	Unk		Not Reported
	Acetaminophen			C	Oral	Unk		Not Reported

Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Ferrous Gluconate		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Lasilix [Furosemide]		C	Unknown	Unk	Not Reported
	Methylprednisolone		C	Intravenous (not otherwise specified)	Unk	Not Reported
	Naprosyn [Naproxen Sodium]		C	Unknown	Unk	Not Reported
	Oxycontin		C	Unknown	Unk	Not Reported
	Oxyneo		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236376	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-002876			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragm Muscle Weakness; Encephalopathy; Myopathy Toxic; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Respiratory Failure; Septic Shock	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Anakinra			C	Subcutaneous	100 Milligram, Qd		Not Reported
	Hydrocortisone			C	Unknown	20 Milligram In The Morning		Not Reported
	Hydrocortisone			C	Unknown	10 Milligram In The Afternoon		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236552	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Etanercept			C	Unknown	Unk		Not Reported

Arthritis	Humira	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236790	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-05444		43 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Oseltamivir			S	Endocervical	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Levetiracetam			C	Unknown	Unk		Not Reported
	Heparin			C		Unk (Low Molecular Weight)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236815	EXPEDITED (15-DAY)		HO, LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-040		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Embolic Stroke; Encephalopathy; Endocarditis; Fall; Hypercapnia; Muscle Injury; Myopathy; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Subarachnoid Haemorrhage; Tibia Fracture; Toxicity To Various Agents	Hydrocortisone			S	Unknown			Hikma
	Hydrocortisone			S	Unknown			Hikma
	Hydroxychloroquine			S	Unknown			Hikma
	Anakinra			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236900	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259769		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Sun
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236901	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259771		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Sun
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236902	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259770			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Sun
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236903	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259766		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine	S	Unknown	Unk		Sun
	Remdesivir	S	Unknown	Unk		Not Reported
	Betamethasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236906	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259772			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Sun
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237365	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05550		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Darunavir			S	Unknown	800 Milligram, Qd		Not Reported
	Rivaroxaban			C	Unknown	20 Milligram, Qd		Not Reported
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported
	Ritonavir			C	Unknown	100 Milligram, Qd		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Sildenafil			C	Unknown	60 Milligram, Qd		Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237391	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS		73 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Oseltamivir			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Meropenem			C	Unknown	Unk		Not Reported
	Linezolid			C	Unknown	Unk		Not Reported
	Levofloxacin			C	Unknown	Unk		Not Reported
	Kaletra			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237404	EXPEDITED (15-DAY)		OT	CA-ACCORD-199554		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Methotrexate			S				Accord
	Apo-Leflunomide			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Salazopyrin			S				Not Reported
	Apo-Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237480	EXPEDITED (15-DAY)		DS	CA-ACCORD-199550		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Oral			Accord
	Apo-Leflunomide			S	Oral	Frequency: 1 Every 1 Days		Not Reported

Apo-Prednisone	S	Oral	Frequency: 1 Every 1 Days		Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
Hydroxychloroquine	S		Frequency: 1 Every 1 Days		Not Reported
Indometacin	S				Not Reported
Leflunomide	S	Oral	Frequency: 1 Every 1 Days		Not Reported
Prednisone	S	Oral	Frequency: 1 Every 1 Days		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral	Frequency: 2 Every 1 Days		Not Reported
Xeljanz	C				Not Reported
Folic Acid	C				Not Reported
Cymbalta	C				Not Reported
Hydroxychloroquine	S		Frequency: 1 Every 1 Days		Not Reported
Methotrexate	S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237512	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05598		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ceftriaxone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237527	EXPEDITED (15-DAY)		HO, OT	TR-ACCORD-199650		65 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Hydroxychloroquine			S				Not Reported
	Azithromycin			S				Not Reported
	Favipiravir			S				Not Reported
	Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237529	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-198985		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Sinus Bradycardia	Hydroxychloroquine			S				Not Reported
	Dexmedetomidine/Dexmedetomidine Hydrochloride			S				Not Reported
	Azithromycin			S				Not Reported
	Propofol			S				Not Reported
	Epinephrine			C		Cardiopulmonary Resuscitation Using 2 Doses Of 1 Mg		Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237640	EXPEDITED (15-DAY)		OT	CA-ACCORD-199474		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness;	Methotrexate			S	Oral			Accord
	Apo-Leflunomide			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution		Not Reported

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress				Subcutaneous	
	Hydroxychloroquine	S			Not Reported
	Leflunomide	S			Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Sulfasalazine	S			Not Reported
	Tylenol	C			Not Reported
	Prednisone	C	Oral	Frequency: 1 Every 1 Days	Not Reported
	Mefenamic Acid	C			Not Reported
	Dequalinium	C			Not Reported
	Enbrel	S	Subcutaneous	Frequency: 1 Every 1 Weeks	Not Reported
	Hydroxychloroquine	S	Oral	Hydroxychloroquine Sulfate	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Hydroxychloroquine Sulfate, Frequency: 1 Every 2 Weeks	Not Reported
	Prednisone	C	Oral	Frequency: 1 Every 1 Days	Not Reported
	Prednisone	C	Oral	Frequency: 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237641	EXPEDITED (15-DAY)		HO	CA-ACCORD-199464		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia;	Methotrexate			S	Subcutaneous			Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Hydroxychloroquine	S	Unknown			Not Reported
	Naproxen	S	Unknown	3 Every 1 Days		Not Reported
	Penicillin G	S	Unknown			Not Reported
	Levothyroxine	C				Not Reported
	Tramadol	C				Not Reported
	Hydroxychloroquine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237663	EXPEDITED (15-DAY)		OT	CA-ACCORD-199539		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237664	EXPEDITED (15-DAY)		OT	CA-ACCORD-199540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Minocycline	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Unknown	2 Every 1 Days		Not Reported
Hydroxychloroquine	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237665	EXPEDITED (15-DAY)		OT	CA-ACCORD-199541		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Treatment Failure; Uveitis	Methotrexate			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Golimumab			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Rabeprazole			C	Oral	1 Every 24 Hours		Not Reported

	Prednisone	C	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237667	EXPEDITED (15-DAY)		OT	CA-ACCORD-199568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			C				Not Reported
	Desoximetasone			C	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Ibuprofen			C	Unknown	Not Specified		Not Reported
	Naproxen			C	Unknown	Not Specified		Not Reported
	Prednisone			C	Oral	1 Every 1 Days		Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C		1 Every 1 Days		Not Reported
	Tramadol			C	Oral	3 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237670	EXPEDITED (15-DAY)		OT	CA-ACCORD-199609		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue;	Methotrexate			S				Accord
	Prednisone			S				Not Reported
	Arava			S				Not Reported

Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237671	EXPEDITED (15-DAY)		OT	CA-ACCORD-199606			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237673	EXPEDITED (15-DAY)		OT	CA-ACCORD-199610			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain;	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Arava			S		1 Every 1 Days		Not Reported
	Azathioprine			S		Subcutaneous,3 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported

Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Neoral		S		2 Every 1 Days	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral	2 Every 1 Days	Not Reported
	Citalopram		C		1 Every 1 Weeks	Not Reported
	Prednisone		C			Not Reported
	Methotrexate		S	Oral	1 Every 1 Weeks	Accord
	Citalopram		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237676	EXPEDITED (15-DAY)		OT	CA-ACCORD-199613		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution, Single-Use Prefilled Syringe		Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237851	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-222027		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine	S	Unknown	200 Milligram, Daily	Sun
	Paxil	C	Unknown	Unk	Not Reported
	Aspirin	C	Unknown	Unk	Not Reported
	Vitamin D	C	Unknown	Unk	Not Reported
	Montelukast	C	Unknown	Unk	Not Reported
	Flomax	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237928	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SF11670			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18237939	EXPEDITED (15-DAY)		OT	CA-ACCORD-199552		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Methotrexate			S				Accord
	Arava			S				Not Reported
	Humira			S	Subcutaneous	Frequency: 1 Every 2 Weeks, Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Frequency: 1 Every 1 Days		Not Reported
	Orencia			S				Not Reported

	Rituximab		S	Intravenous drip		Not Reported
	Simponi		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Sulfasalazine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18238133	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2020-025067		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intensive Care Unit Acquired Weakness; Myopathy	Hydrocortisone			S	Unknown	20 Mg Every Morning And 10 Mg Every Afternoon (Started At The Age Of 18 Years)		Not Reported
	Hydrocortisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Patient Was On A Stable Dose From Age 40 To 42 Years		Not Reported
	Anakinra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18238137	EXPEDITED (15-DAY)		OT	QA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260122		28 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
	Azithromycin			S	Unknown	500 Milligram, Daily		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18238151	EXPEDITED (15-DAY)		OT	MA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260084		76 YR	Female	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown			Sun
	Azithromycin			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18238398	EXPEDITED (15-DAY)		HO	NVSC2020US243587		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Condition Aggravated; Product Use In Unapproved Indication; Respiratory Failure; Seizure; Septic Shock	Azithromycin			S	Unknown			Novartis
	Ceftriaxone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18238646	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017020			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Vomiting	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Leflunomide			S	Unknown	Unk Unk, Qd		Apotex
	Baricitinib			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18238746	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2020336919		48 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram T Wave Inversion; Hepatic Enzyme	Tazobac			S	Intravenous (not otherwise specified)	4500 Mg, 2x/Day		Pfizer

Increased; Hyperbilirubinaemia; Jaundice	Reyataz	S	Oral	400 Mg, 1x/Day	Not Reported
	Tarivid [Ofloxacin]	S	Oral	Unk	Not Reported
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]	S	Oral	Unk	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, 1x/Day	Not Reported
	Cefepime	S	Intravenous (not otherwise specified)	2 G, 3x/Day	Not Reported
	Supracyclin [Doxycycline Monohydrate]	S	Oral	1 Df, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day (400 Mg 2x / D On 23 And 24.03.2020 Then 200 Mg 2x / D)	Not Reported
	Dafalgan	S	Oral	500 Mg, As Needed (500 Mg (1 To 4x / Day If Necessary)	Not Reported
	Paracetamol	S		1500-2000 Mg, Daily	Not Reported
	Paracetamol	S		1000 Mg, Daily	Not Reported
	Clexane	S	Subcutaneous	40 Mg, 1x/Day	Not Reported
	Midazolam	S		Unk (Dosage Variables)	Not Reported
	Fentanyl	S		Unk (Dosage Variables)	Not Reported
	Propofol	S		Unk (Dosage Variables)	Not Reported
	Rocuronium	S		Unk (Dosage Variables)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18238799	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200844167			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Fatigue; Joint Swelling; Nausea; Product Dose Omission; Quality Of Life Decreased; Rheumatoid Arthritis; Rheumatoid Factor	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Positive; Skin Discolouration; Visual Impairment; Vomiting	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18239269	EXPEDITED (15-DAY)		OT	NVSC2020ES241082		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Nausea	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Azithromycin Dihydrate			S	Unknown	Unk		Not Reported
	Ceftriaxona			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18239378	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SF12450			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Ceftazidime			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Mycophenolic Acid			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Ventolin			C				Not Reported
	Tylenol			C				Not Reported
	Slow K			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Risedron			C				Not Reported
	Pantoloc			C				Not Reported
	Pantoprazole			C				Not Reported

	Metoprolol	C	Not Reported
	Methylprednisolone	C	Not Reported
	Metformin	C	Not Reported
	Januvia	C	Not Reported
	Insulin Lispro	C	Not Reported
	Hydrochlorothiazide	C	Not Reported
	Escitalopram	C	Not Reported
	Eprex	C	Not Reported
	Diphenhydramine	C	Not Reported
	Acetaminophen	C	Not Reported
	Amiodarone Hydrochloride	C	Not Reported
	Piperacilina + Tazobactam	C	Not Reported
	Potassium Chloride	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18239684	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1824134		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18239714	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824823		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Off Label Use; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	13406867	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2017142138		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Lung Disorder; Skin Lesion; Therapeutic Product Effect Incomplete; Total Lung Capacity Decreased	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Unknown	400 Mg, 5 Days Per Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	13974929	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP018008			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Hydroxyquine			S				Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Leflunomide			S				Apotex
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported

	Ilaris	S				Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S				Not Reported
	Rituxan	S	Unknown			Not Reported
	Rituxan	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	14630900	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2018AP007493		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During	Apo-Prednisone			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Oral	Unk (Therapy Duration 365 Unit Unspecified)		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Apo-Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Alendronate			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	Unk		Not Reported

Pregnancy; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	1 Gram, Bid	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unit Unspecified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Therapy Duration: 365 Unspecified Unit)	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	2 Gram, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid (Therapy Duration 365 Unit Unspecified)	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported

Cortisone	S	Oral	Unk		Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Sulfathalidine	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid		Not Reported
Topicort /00028604/	S	Cutaneous	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Bid		Not Reported
Xeljanz	S				Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported
Atasol /00020001/	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	15956472	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190209141		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; C-Reactive Protein Increased; Crohn'S Disease; Decreased Appetite; Drug Ineffective; Drug Intolerance; Exostosis; Fatigue; Foot Deformity; Hepatic Cirrhosis; Hypoaesthesia;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled		Not Reported

Joint Dislocation; Joint Stiffness; Malaise; Mobility Decreased; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pain In Extremity; Rash; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Humira	S	Syringe	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Oral	Not Reported
	Otezla	S	Unknown	Not Reported
	Adalimumab	S	Oral	Not Reported
	Leflunomide	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Oral	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Minocycline	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sirukumab	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
			Unknown	Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Golimumab	S	Subcutaneous	Not Reported
	Ustekinumab	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Bupropion Hydrochloride	C		Not Reported
	Hydromorphone Hydrochloride	C		Not Reported
	Bupropion	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	15957816	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190213604		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Ankylosing Spondylitis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Gait Inability; Hypermobility Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Nausea; Rheumatoid Arthritis; Somnolence; Unevaluable Event; Vertigo; Visual Impairment; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Duragesic			S	Unknown			Not Reported
	Duragesic			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Actemra	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Celebrex	S	Oral	Not Reported
Cosentyx	S	Unknown	Not Reported
Gabapentin	S	Unknown	Not Reported
Gabapentin	S	Unknown	Not Reported
Gabapentin	S	Unknown	Not Reported
Hydromorphone	S	Unknown	Not Reported
Hydromorphone	S		Not Reported
Hydromorphone	S		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Lolo	C	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Indomethacin /00003801/	C	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	15960760	EXPEDITED (15-DAY)		OT	CA-ROCHE-1195070			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Aphthous Ulcer; Aphthous Ulcer; Flatulence; Intentional Product Use Issue; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous	Suspended		Not Reported
	Actemra			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Tramadol			C				Not Reported
	Percocet			C				Not Reported
	Feramax			C				Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported
	Percocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	16798073	EXPEDITED (15-DAY)		DE, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-219564		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Pulmonary Oedema; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	60 Tablets		Sun
	Ibuprofen			S	Unknown	Unk		Sun
	Naproxen			S	Unknown	Unk (750mg)		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	16848127	EXPEDITED (15-DAY)		HO, OT	PH-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-221530		47 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Aneurysm; Infective Aortitis; Renal Haemorrhage	Hydroxychloroquine			S	Unknown	200 Milligram, Od		Sun
	Prednisone			S	Unknown	1 Milligram/Kilogram, Daily		Mutual
	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	500 Milligram, Bid		Not Reported
	Atorvastatin			C	Unknown	40 Milligram, Od		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	17572131	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332786		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	17731644	EXPEDITED (15-DAY)		HO, LT, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245540		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Drug Level Increased	Tacrolimus	S	Unknown	5 Milligram, Bid	Not Reported
	Tacrolimus	S	Unknown	3 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Sun
	Lopinavir/Ritonavir	S	Unknown	400 Mg/100 Mg , Bid	Not Reported
	Cobicistat/Darunavir	S	Unknown	800 Mg/150 Mg	Not Reported
	Methylprednisolone	C	Unknown	4 Milligram, Daily	Not Reported
	Methylprednisolone	C	Unknown	6.5 Milligram, Daily	Not Reported
	Omeprazole	C	Unknown	20 Milligram, Daily	Not Reported
	Allopurinol	C	Unknown	150 Milligram, Daily	Not Reported
	Atorvastatin	C	Unknown	20 Milligram, Daily	Not Reported
	Ramipril	C	Unknown	6.5 Milligram, Daily	Not Reported
	Ceftriaxone	C	Unknown	2 Gram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	17766041	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2020AP010461		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.O.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Intravenous (not otherwise specified)	15 Mg, Unk		Not Reported
	Etanercept			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Etanercept			S	Subcutaneous	15 Milligram, Q.O.Wk.		Not Reported

Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Q.M.T.	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	420 Mg, Unk	Not Reported
	Rituximab	S	Intravenous drip	420 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	17885783	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200611646		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Alendronate Sodium	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Once Daily (Qd)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	40 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported

	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Golimumab	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Diclofenac	C	Unknown	50 Milligram	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	17980913	EXPEDITED (15-DAY)		OT	CA-ACCORD-188342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Accord
	Metaraminol			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C		Not Reported
	Methotrexate	S	Subcutaneous	Accord
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	17987097	EXPEDITED (15-DAY)		OT	CA-ACCORD-188449			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Methotrexate			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Prefilled Syringe		Not Reported
	Etanercept			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Mefenamic Acid			S				Not Reported
	Orencia			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C		1 Every 24 Hours		Not Reported
	Tylenol			C				Not Reported
	Paracetamol			C				Not Reported
	Prednisone			C	Oral	1 Every 24 Hours		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			C	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18042763	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020ES200792		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Pressure Increased; Clonus; Delirium; Depressed Level Of Consciousness; Drug Interaction; Encephalopathy; Hyperhidrosis; Hyperreflexia; Hypertension; Myoclonus; Off Label Use; Serotonin Syndrome; Tachycardia; Urinary Retention	Duloxetine			S	Oral	120 Mg, Qd		Not Reported
	Duloxetine			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg Twice Daily		Novartis
	Lopinavir,Ritonavir			S	Oral	2 Df, Qd		Not Reported
	Lopinavir,Ritonavir			S	Unknown	400 Mg/100 Mg Twice Daily		Not Reported
	Haloperidol			S	Oral	2 Mg, Qd		Not Reported
	Haloperidol			S	Unknown	1 Mg Twice Daily		Not Reported
	Lithium			S	Oral	800 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18112062	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202007007512			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Cataract; Diabetes Mellitus; Mobility Decreased; Nail Disorder; Pain In Extremity; Stress; Visual Impairment	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	(40 Mg, 1 In 14 D)		Not Reported
	Prednisone			C		Unk		Not Reported
	Humalog 75/25			C		Unk, Strength: 75/25		Not Reported
	Lantus			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Propranolol			C		Unk		Not Reported
	Betamethasone			C		Unk		Not Reported

	Omeprazole	C	Unk		Not Reported
	Omeprazole	C			Not Reported
	Omeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18201600	EXPEDITED (15-DAY)		HO	CA-ACCORD-197108			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution, 1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18204001	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200831638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous drip			Not Reported

Cimzia	S	Subcutaneous		Not Reported
Cosentyx	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Otezla	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Arava	C	Unknown		Not Reported
Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18207177	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200834214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18214401	EXPEDITED (15-DAY)		DE, HO, LT, OT	CN-PFIZER INC-2020333553		64 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Test Positive; Penicillium Infection; Pneumonia	Methylprednisolone			S		24 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		0.2 G, 2x/Day (Freq:12 H)		Not Reported
	Ciclosporin			S		50 Mg, 2x/Day (Freq:12 H)		Not Reported
	Amlodipine			C		5 Mg, 1x/Day		Not Reported
	Warfarin			C		2.5 Mg, 1x/Day		Not Reported
	Potassium Chloride			C		0.5 G, 1x/Day		Not Reported
	Torasemide			C		10 Mg, 1x/Day		Not Reported
	Febuxostat			C		40 Mg, 1x/Day		Not Reported
	Sodium Bicarbonate			C		0.5 G, 3x/Day (Freq:8 H)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18216864	EXPEDITED (15-DAY)		OT	CA-ACCORD-198177			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Methotrexate			S	Subcutaneous			Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Minocycline			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported
	Arava			S				Not Reported
	Amoxil			C				Not Reported
	Amoxicillin Trihydrate/Clavulanate			C				Not Reported

	Potassium				
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18239511	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1824926			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18239519	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017113			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Nausea; Renal Failure	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Methotrexate			S	Unknown	20 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18239678	EXPEDITED (15-DAY)		HO	IT-ROCHE-2672334		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Creatinine Increased; Covid-19 Pneumonia; Drug Trough Level; Nausea; Vomiting	Mycophenolate Mofetil			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Basiliximab			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Darunavir			S	Unknown			Not Reported
	Cobicistat			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Envarsus			S	Unknown			Not Reported
	Envarsus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Cyclosporin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18239800	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824206		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			C	Unknown	2.5 Milligram Daily;		Not Reported
	Gabapentin			C	Unknown	400 Milligram Daily;		Not Reported

	Prednisone		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18239818	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825741		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18239873	EXPEDITED (15-DAY)		OT	IR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260106		43 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Levetiracetam			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Oseltamivir			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18239970	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259747		28 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose;	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Sun

Asthenia; Diarrhoea; Electrocardiogram Qt Prolonged; Nausea; Sinus Bradycardia	Oseltamivir		C	Oral	75 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240198	EXPEDITED (15-DAY)		OT	CA-ACCORD-199614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240199	EXPEDITED (15-DAY)		DS	CA-ACCORD-199544		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240200	EXPEDITED (15-DAY)		OT	CA-ACCORD-199617		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Parenteral			Not Reported
	Arava			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous, Frequency: 1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240209	EXPEDITED (15-DAY)		OT	CA-ACCORD-199548		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate			S				Accord
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		Frequency: 1 Every 24		Not Reported

			Hours	
	Gabapentin	C	Frequency: 2 Every 1 Days	Not Reported
	Amlodipine	C	Frequency: 1 Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240214	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-046623		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Lopinavir/Ritonavir			C	Unknown	200 Milligram, Two Times A Day		Not Reported
	Ceftriaxone			C	Unknown	2 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240376	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-05581		35 DAY	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	10 Milligram/Kilogram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	15 Milligram/Kilogram, Qod (Every Six Hours)		Lupin
	Hydroxychloroquine			S	Unknown	30 Milligram/Kilogram, Qod (Every Eight Hours)		Lupin
	Hydroxychloroquine			S	Unknown	12 Milligram Bid (Every 12 Hours)		Lupin
	Hydroxychloroquine			S	Unknown	12 Milligram Bid (Every 12 Hours)		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

	Oseltamivir	S	Unknown	Unk	Lupin
	Vancomycin	S	Unknown	Unk	Lupin
	Salbutamol	C	Unknown	Unk (He Received Two Puffs Of Salbutamol Every 20 Minutes Three Times)	Not Reported
	Salbutamol	C	Unknown	Unk (He Received Two Puffs Of Salbutamol Every Four Hours Three Times)	Not Reported
	Meropenem	C	Unknown	30 Mg/Kg/Dose Tid (Every Eight Hours)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240417	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Leflunomide			S	Unknown	200 Milligram, Bid		Apotex
	Leflunomide			S	Unknown	20 Milligram, Bid		Apotex
	Methotrexate			C	Oral	20 Milligram		Not Reported
	Methotrexate			C	Intramuscular	20 Milligram		Not Reported
	Aspirine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Q.12h		Not Reported
	Asa Ec			C	Unknown	650 Milligram, Q.12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824132		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Insomnia; Rheumatoid	Methotrexate			S	Unknown			Barr

Arthritis	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Folic Acid	C			Not Reported
	Hydrodiuril	C	Unknown	12.5 Milligram Daily;	Not Reported
	M-Eslon	C	Unknown	20 Milligram Daily;	Not Reported
	Morphine	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Venlafaxine Hydrochloride	C	Unknown	37.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240626	EXPEDITED (15-DAY)		OT	CA-ACCORD-199678			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S				Accord
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S		Frequency: 1 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituximab			S				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240631	EXPEDITED (15-DAY)		OT	CA-ACCORD-199623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury;	Methotrexate			S	Unknown			Not Reported

Dyspepsia	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Simponi	S	Unknown	Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18240714	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-047044			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Fibrillation; Ventricular Tachycardia	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241451	EXPEDITED (15-DAY)		HO, OT	IN-LUPIN PHARMACEUTICALS INC.-2020-05559		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Face Oedema; Lymphadenopathy; Oedema Peripheral	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk, Restarted		Lupin
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241497	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824862		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness;	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Unknown	20 Milligram Daily;	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Oral	11 Milligram Daily;	Not Reported
	Xeljanz Xr	C	Oral	11 Milligram Daily;	Not Reported
	Xeljanz Xr	C	Oral	11 Milligram Daily;	Not Reported
	Xeljanz Xr	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241531	EXPEDITED (15-DAY)		OT	CA-ACCORD-199733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241569	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824546		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate	S	Parenteral	Barr
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Azathioprine	C		Not Reported
	Ciclosporin	C		Not Reported
	Minocycline	C		Not Reported
	Penicillamine	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824961		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased;	Methotrexate			S	Unknown			Barr

Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Arava	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Lyrica	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Bimatoprost	C	Ophthalmic		Not Reported
	Esomeprazole	C	Unknown	40 Milligram Daily;	Not Reported
	Nexium	C	Unknown	40 Milligram Daily;	Not Reported
	Sulfasalazine	C	Unknown	2000 Milligram Daily;	Not Reported
	Suphedrine	C	Unknown	10 Milligram Daily;	Not Reported
	Trazodone	C	Unknown	200 Milligram Daily;	Not Reported
	Tylenol	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241626	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported
	Alendronate Sodium/Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Cortisone	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S			Not Reported
	Diclofenac Sodium	S			Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Tocilizumab	S			Not Reported
	Leflunomide	C			Not Reported
	Paracetamol And Codeine Phosphate (I)	C			Not Reported
	Caffeine Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241639	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05589		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

	Tocilizumab	C	Unknown	400 Milligram, Unk	Not Reported
	Nitric Oxide	C	Unknown	Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
	Enoxaparin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241654	EXPEDITED (15-DAY)		OT	CA-ACCORD-199619			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241655	EXPEDITED (15-DAY)		DS, HO, OT	CA-ACCORD-199616		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Factor Positive; Therapeutic Product Effect	Methotrexate			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Indometacin			S				Not Reported
	Leflunomide			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S				Not Reported

Decreased; Treatment Failure	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral	Frequency: 2 Every 1 Days	Not Reported
	Methotrexate		S	Subcutaneous	Frequency: 1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241658	EXPEDITED (15-DAY)		OT	CA-ACCORD-199691		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	1 Every 1 Months		Not Reported
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S				Accord
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported
	Prednisone			C	Unknown	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241669	EXPEDITED (15-DAY)		OT	CA-ACCORD-199618		89 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Oral			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Oral	Frequency: 1 Every 24 Hours		Not Reported
	Enbrel			S		Frequency: 2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Naproxyn			S	Oral	Frequency:2 Every 1 Days		Not Reported
	Orencia			S				Not Reported
	Rituximab			S				Not Reported
	Vioxx			S				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	Frequency: 2 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241707	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824128		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Kevzara	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241744	EXPEDITED (15-DAY)		OT	CA-ACCORD-199744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	1 Every 24 Hours		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Simponi			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241754	EXPEDITED (15-DAY)		HO, OT	TR-ACCORD-199772		47 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Myasthenia	Hydroxychloroquine			S		1 Dose Of Hcq		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241831	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1076022		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Diarrhoea; Drug Interaction; Gastrointestinal Toxicity; Glomerular Filtration Rate Abnormal; Nausea; Off Label Use; Overdose; Toxicity To Various Agents	Tacrolimus			S	Unknown	5 Milligram, Bid		Mylan
	Tacrolimus			S	Unknown	3 Milligram, Bid		Mylan
	Lopinavir/Ritonavir			S	Unknown	1 Dosage Form, Bid		Mylan
	Lopinavir/Ritonavir			S				Mylan
	Ceftriaxone			S	Unknown	2 Gram, Qd		Not Reported
	Methylprednisolone			S	Unknown	4 Milligram, Qd		Mylan
	Methylprednisolone			S	Unknown	Dose Of Methylprednisolone Was Increased To 6.5 Mg Daily, And Continued		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Mylan
	Cobicistat W/Darunavir			S	Unknown	Unk		Mylan
	Omeprazole			C	Unknown	20 Milligram, Qd		Mylan
	Allopurinol			C	Unknown	150 Milligram, Qd		Mylan
	Atorvastatin			C	Unknown	20 Milligram, Qd		Mylan
	Ramipril			C	Unknown	2.5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241912	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825304		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241946	EXPEDITED (15-DAY)		OT	NVSC2020US244712		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjacent Segment Degeneration	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis
	Prednisone			C	Unknown	5.8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242177	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05624		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242246	EXPEDITED (15-DAY)		OT	CA-ACCORD-199738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral	1 Every 1 Days		Accord
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Myochrysine			S	Intramuscular	1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242248	EXPEDITED (15-DAY)		OT	CA-ACCORD-199686		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown	Not Specified		Accord
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	2 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242249	EXPEDITED (15-DAY)		OT	CA-ACCORD-199683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	1 Every 1 Weeks, Not Specified		Accord
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Infliximab			S	Oral	1 Every 1 Days		Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoloc			C	Oral	1 Every 1 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242257	EXPEDITED (15-DAY)		OT	CA-ACCORD-199543		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C	Unknown	1 Every 1 Days		Not Reported
	M-Eslon			C	Unknown	2 Every 1 Days		Not Reported

	Morphine	C	Unknown		Not Reported
	Venlafaxine	C	Unknown	1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242258	EXPEDITED (15-DAY)		OT	CA-ACCORD-199679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate			S	Unknown			Accord
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242382	NON-EXPEDITED			US-009507513-2008USA012812		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242706	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2019SE31046		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Crestor	S	Oral			Astrazeneca
	Crestor	S	Oral			Astrazeneca
	Crestor	S	Oral			Astrazeneca
	Enbrel	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Arava (Leflunomide)	S	Unknown			Not Reported
	Gold(Gold)	S	Unknown			Not Reported
	Orencia (Abatacept)	S	Unknown			Not Reported
	Remicade(Infliximab)	S	Intravenous (not otherwise specified)			Not Reported
	Actemra (Tocilizumab)	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242847	NON-EXPEDITED			US-009507513-2009USA002560		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Dexamethasone			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243340	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SF11504		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cardiac Disorder; Contusion; Croup Infectious; Drug Ineffective; Fatigue; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased; Hypersensitivity; Hypertension; Hypotension; Immunosuppression; Influenza; Infusion Related Reaction; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pain; Pain In Extremity; Pertussis; Productive Cough; Rash; Stress; Therapeutic Response Decreased; Treatment Failure; Weight Decreased; Weight Increased	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Humalog			C				Not Reported
	Sertraline Hydrochloride			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243377	NON-EXPEDITED			US-009507513-2009USA002561		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243482	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1825307			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243655	EXPEDITED (15-DAY)		HO	IN-AMNEAL PHARMACEUTICALS-2020-AMRX-02686		32 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Hydroxychloroquine Sulfate			S	Unknown	1st Dose 800 Mg On First Day		Amneal
	Hydroxychloroquine Sulfate			S	Unknown	2nd Dose 400 Mg After 1		Amneal

					Week And Same Dose In 3rd Week	
	Pyridostigmine		C	Unknown	Unk (Sos)	Not Reported
	Pyridostigmine		C	Unknown	180 Milligram, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243684	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202008008438			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Lymphoma	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243690	NON-EXPEDITED			US-009507513-2009USA002563		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243712	NON-EXPEDITED			US-009507513-2009USA002562		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243990	EXPEDITED (15-DAY)		OT	NVSC2020US246099		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18246294	DIRECT	N				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive	Plaquenil Tab 200mg			S	Oral			Not Reported
	Simponi Aria			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18281683	DIRECT		DE			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication; Product Use Issue; Renal Transplant; Suspected Covid-19	Lopinavir-Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Dexamethasone			S				Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18281756	DIRECT					59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pericardial Effusion; Respiratory Failure; Respiratory Tract Infection	Lopinavir-Ritonavir			S				Not Reported
	Enoxaparin			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18281825	DIRECT		DE			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Lactic Acidosis; Off Label Use; Respiratory Tract Infection	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18281942	DIRECT		DE			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardiac Arrest; Circulatory Collapse; Foetal Death; Foetal Exposure During Pregnancy; Haemodialysis; Maternal Exposure During Pregnancy; Pneumothorax; Pneumothorax; Product Use Issue	Hydroxychloroquine			S				Not Reported
	Oseltamivir			S				Not Reported
	Azithromycin			S				Not Reported
	Lopinavir-Ritonavir			S				Not Reported
	Ceftriaxone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	13058853	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015743		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea;	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Mg, Unk	Not Reported
	Rituximab;Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Elavil /00002202/	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Imitrex /01044801/	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Sumatriptan Succinate	C	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	13254330	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006769		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	14235040	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2017AP021690		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.Wk.		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	50 Mg, Bid		Not Reported

	Hydroxychloroquine Sulfate			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	16061828	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020940		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	16769626	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2908030-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease;	Humira			S	Subcutaneous			Not Reported
	Clavulin			S	Unknown			Not Reported

Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine		S	Unknown		Not Reported
	Ciprofloxacin		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Solution	Not Reported
	Mycophenolate Mofetil		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Amoxicillin Sodium W/Clavulanate Potassium		S	Unknown		Not Reported
	Plaquenil		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Tridural		C	Unknown	Prolonged Release Tablet	Not Reported
	Tylenol		C	Unknown		Not Reported
	Hydroxychloroquine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	17233853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Unknown			Not Reported

Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 823.0	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tylenol	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration: 183.0 Days	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Celecoxib	C			Not Reported
	Hydromorphone Hcl	C			Not Reported
	Meloxicam	C			Not Reported
	Methotrexate	C			Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	17245567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512065		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	17807048	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599975		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Neoral	S	Subcutaneous		Not Reported
Neoral	S	Oral		Not Reported
Neoral	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Plaquenil	S	Oral	Df: Dosage Form	Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported

	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	17869186	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP011878		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	1 Df, Qd		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Tramadol/Acetaminophen			S	Oral	Unk		Apotex
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Tramacet			S	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported

Lorazepam	C	Unknown	1 Mg, Qd	Not Reported
Lyrica	C	Oral	150 Mg, Bid	Not Reported
Metformin	C	Unknown	5 Mg, Qd	Not Reported
Metformin	C	Unknown	500 Mg, Bid	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Mg, Q.M.T.	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk Unk, Q.M.T.	Not Reported
Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	20 Mg, Qd	Not Reported
Nortriptyline	C			Not Reported
Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
Risedronate Sodium	C	Unknown	35 Mg, Q.Wk.	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	17943163	EXPEDITED (15-DAY)		HO, LT, OT	ES-ELI_LILLY_AND_COMPANY-ES202006009361		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Pressure Increased; Clonus; Delirium; Depressed Level Of Consciousness; Drug Interaction; Encephalopathy; Hyperhidrosis; Hyperreflexia; Myoclonus; Off Label Use; Serotonin Syndrome; Speech Sound Disorder; Tachycardia;	Duloxetine Hydrochloride			S	Oral	120 Mg, Per Day		Eli Lilly And Co
	Duloxetine Hydrochloride			S				Eli Lilly And Co
	Lopinavir;Ritonavir			S	Oral	1 Dosage Form, Bid		Not Reported
	Lithium			S	Oral	800 Mg, Daily		Not Reported
	Haloperidol			S	Oral	1 Mg, 2x Per Day		Not Reported
	Haloperidol			S	Unknown	1 Mg Twice Daily		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x Per Day		Not Reported

Urinary Retention

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18031448	EXPEDITED (15-DAY)		HO, LT, OT	IN-ACCORD-190186		32 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis; Tachycardia; Tachypnoea	Hydroxychloroquine			S		1 Dose 800 Mg On First Day, Second Dose 400 Mg After 1 Week, And The Same Dose In 3 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18080330	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2020AP014253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	12.5 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18113184	EXPEDITED (15-DAY)		OT	US-SUN		41 YR	Female	USA

PHARMACEUTICAL INDUSTRIES LTD-2020R1-255161

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Cerebral Infarction; Eclampsia; Exposure During Pregnancy; Foetal Death; Hellp Syndrome; Sepsis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Sun
	Tocilizumab			S	Unknown	Two Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18115596	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2020294023		65 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Plaquinol			S	Oral	400mg Of 12/12h On D0 After 200mg 12/12h		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	20 Mg, 1x/Day		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Quetiapine			C	Oral	Unk		Not Reported
	Esomeprazole			C	Oral	40 Mg, 1x/Day		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	4 Inhalations 6 / 6h		Not Reported
	Trazodone			C	Oral	50 Mg, 1x/Day		Not Reported
	Levothyroxine Sodium			C	Oral	50 Ug, 1x/Day		Not Reported
	Piperacilin/Tazobactam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Clonidine			C	Oral	0.15 Mg, 1x/Day		Not Reported
	Salbutamol			C	Respiratory	6 Inhalations 4 / 4h		Not Reported

	Escitalopram		C	(inhalation) Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18117793	EXPEDITED (15-DAY)		HO, OT	NVSC2020US214647		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Cyclosporine			S	Intravenous (not otherwise specified)	2 Mg/Kg Continous Infusion		Novartis
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18150140	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017765		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Rheumatoid Arthritis; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Advil /00044201/			C	Unknown	Unk		Not Reported

Folic Acid	C	Unknown	Unk		Not Reported
Ketorolac	C	Unknown	Unk		Not Reported
Naproxen /00256202/	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk		Not Reported
Acetaminophen;Codeine	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	20 Milligram		Not Reported
Advil [Ibuprofen]	C	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qd		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18198796	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1818269			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cardiomegaly; End Stage Renal Disease; Maculopathy; Prescribed Overdose; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	300 Milligram Daily; 6.5mg/Kg Per Day		Teva
	Hydroxychloroquine			S	Unknown	8.2mg/Kg Per Day		Teva
	Prednisone			C	Unknown			Not Reported
	Mycophenolate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18205029	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025574			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy;	Rituximab (Unknown)			S	Intravenous (not	Unk		Not Reported

Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal			otherwise specified)			
	Actemra	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Mg 1 Every 1 Day		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Oral	20.0 Mg 1 Every 1 Week		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1.0 Dosage Form		Not Reported
	Prednisone	S	Unknown	10.0 Mg		Not Reported
	Prednisone	S				Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18206608	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA025604			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive	Rituximab (Unknown)			S	Unknown	1000.0 Milligram, 2 Every 1 Days		Not Reported
	Actemra			S	Unknown	360.0 Milligram, 1 Every 1 Months		Not Reported
	Actemra			S	Unknown	680.0 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70.0 Milligram, 1 Every 1		Not Reported

Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer				Weeks	
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Humira	S	Unknown	40.0 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	10.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Oral	10.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18218199	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2020-US-1821478		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lividity; Off Label Use	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported
	Piperacillin /Tazobactam			S	Unknown			Not Reported
	Unfractionated Heparin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18244039	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-046735		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Creatinine Increased; Covid-19 Pneumonia; Drug Trough Level; Labelled Drug-Drug Interaction Medication Error; Nausea; Vomiting	Allopurinol			S	Unknown	150 Milligram, Once A Day		Not Reported
	Atorvastatin			S	Unknown	20 Milligram, Once A Day		Not Reported
	Mycophenolate			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Ramipril			S	Unknown	2.5 Milligram, Once A Day		Aurobindo
	Basiliximab			S	Unknown	Unk		Not Reported
	Cobicistat;Darunavir			S	Unknown	150 Milligram		Not Reported
	Cobicistat			S	Unknown	800 Milligram		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Envarsus			S	Unknown	3 Milligram, Two Times A Day		Not Reported
	Envarsus			S	Unknown	5 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Lopinavir + Ritonavir	S	Unknown	400 Milligram, Two Times A Day		Not Reported
Lopinavir + Ritonavir	S	Unknown	100 Milligram, Two Times A Day		Not Reported
Methylprednisolone	S	Unknown	6.5 Milligram, Once A Day		Not Reported
Methylprednisolone	S	Unknown	4 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18244285	EXPEDITED (15-DAY)		HO	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260463		65 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Favipiravir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18244380	EXPEDITED (15-DAY)		OT	SA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260615		38 YR	Male	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Limb; Pyrexia	Prednisolone			S	Unknown	40 Milligram, Bid		Taro
	Prednisolone			S	Unknown	20 Milligram, Bid		Taro
	Hydroxychloroquine			S	Unknown	Continuous Treatment		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245235	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Methotrexate	S	Unknown		Barr
	Adalimumab	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245236	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824555		89 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral	1000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245252	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245254	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1824558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245588	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-046965		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Condition Aggravated; Covid-19; Off Label Use	Azithromycin	S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo
	Azithromycin	S				Aurobindo
	Hydroxychloroquine	S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Two Times A Day		Not Reported
	Vitamin C	S	Oral	1 Gram, Two Times A Day		Not Reported
	Vitamin C	S				Not Reported
	Zinc Sulfate	S	Unknown	220 Milligram, 3 Times A Day		Not Reported
	Zinc Sulfate	S				Not Reported
	Vitamin C	S	Intravenous (not otherwise specified)	11 Milligram, Once A Day		Not Reported
	Vitamin C	S				Not Reported
	Norepinephrine	C	Unknown	Unk		Not Reported
	Colchicine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245866	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-046967		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Natriuretic Peptide Increased; Haemoglobin Decreased; Off Label Use; Renal Impairment	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Darunavir			S	Unknown	800 Milligram, Once A Day		Not Reported
	Darunavir			S				Not Reported
	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Piperacillin+Tazobactam			S				Aurobindo
	Hydroxychloroquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Ritonavir			S	Unknown	100 Milligram, Once A Day		Not Reported
	Ritonavir			S				Not Reported
	Sildenafil			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported

Rivaroxaban	C	Unknown	Unk		Not Reported
Losartan	C	Unknown	Unk		Not Reported
Enoxaparin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245876	EXPEDITED (15-DAY)		DE, OT	IT-AUROBINDO-AUR-APL-2020-047038			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Off Label Use; Product Used For Unknown Indication	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Two Times A Day, On Day 1		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day, On Days 25		Not Reported
	Tocilizumab			S	Subcutaneous	162 Milligram,In Two Simultaneous Doses		Not Reported
	Tocilizumab			S	Subcutaneous	162 Milligram,One In Each Thigh		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245893	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-047043			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246320	EXPEDITED (15-DAY)		OT	RU-LUPIN PHARMACEUTICALS INC.-2020-05640		62 YR	Male	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fibrin D Dimer Increased; Neutrophil/Lymphocyte Ratio Increased; Off Label Use; Pulmonary Embolism	Methylprednisolone	S	Intravenous (not otherwise specified)	1000 Milligram, Pulse Therapy	Lupin
	Azithromycin	S	Unknown	Unk	Lupin
	Hydroxychloroquine	S	Unknown	Unk	Lupin
	Dexamethasone	S	Unknown	8 Milligram, Bid	Not Reported
	Bromhexine	C	Unknown	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246425	EXPEDITED (15-DAY)		DE	PE-PFIZER INC-2020343805		13 YR	Female	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246598	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259524		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246965	EXPEDITED (15-DAY)		HO, OT	CA-ASTRAZENECA-2020SF12328		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites;	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Ceftazidime			S	Unknown			Not Reported

Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock;	Furosemide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Piperacillin/Tazobactam	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Vancomycin Hydrochloride	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Amiodarone Hydrochloride	C	Unknown	Not Reported
	Apo-Ketorolac	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Escitalopram	C	Unknown	Not Reported
	Humalog	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Slow-K	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Ventolin	C	Unknown	Not Reported

Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246981	EXPEDITED (15-DAY)		OT	CA-ACCORD-199784		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246982	EXPEDITED (15-DAY)		HO	CA-ACCORD-199782		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug	Methotrexate			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Unknown	Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247040	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259767			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Unknown	Unk		Sun
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247129	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling;	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram		Not Reported
	Orencia			S	Intravenous (not			Not Reported

Systemic Lupus Erythematosus; Wound	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S			Not Reported
	Alendronate Sodium		S	Oral		Not Reported
	Cortisone Acetate		S	Topical	25 Milligram	Not Reported
	Desoximetasone		S	Oral		Not Reported
	Diclofenac Sodium		S			Not Reported
	Folic Acid		S		1 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S			Not Reported
	Hydroxychloroquine		S			Not Reported
	Methotrexate Sodium		S			Not Reported
	Phthalylsulfathiazole		S			Not Reported
	Prednisone		S	Oral	Unk	Not Reported
	Prednisone		S			Not Reported
	Pseudoephedrine Hydrochloride		S			Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S		500 Milligram	Not Reported
	Tocilizumab		S	Subcutaneous		Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247144	EXPEDITED (15-DAY)		OT	CA-ACCORD-199785		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247327	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202008008501			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247635	EXPEDITED (15-DAY)		HO, OT	CH-ADVANZ PHARMA-202008008496			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Diarrhoea; Nausea; Type Iv Hypersensitivity Reaction; Urticaria	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247846	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825298			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Zostavax	S	Subcutaneous			Not Reported
Cortisone Acetate	C	Subcutaneous			Not Reported
Desoximetasone	C	Subcutaneous			Not Reported
Diclofenac	C	Subcutaneous			Not Reported
Xeljanz	C	Oral	20 Milligram Daily;		Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247871	EXPEDITED (15-DAY)		HO, OT	CA-ASTRAZENECA-2020SF10768		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Ceftazidime			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	500.0mg Unknown		Not Reported
	Piperacillin Sodium/Tazobactam Sodium			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Plaquenil			S	Unknown	200.0mg Unknown		Not Reported
	Plaquenil			S	Unknown	200.0mg Unknown		Not Reported
	Prednisone			S	Unknown	7.5mg Unknown		Not Reported
	Prednisone			S	Unknown	10.0mg Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000.0mg Unknown	Not Reported
	Vancomycin	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Apo Amlo	C	Unknown		Not Reported
	Apo-K	C	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Epoetin Alfa	C	Unknown		Not Reported
	Escitalopram	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Insulin Lispro	C	Unknown		Not Reported
	Januvia	C	Unknown		Not Reported
	Kcl	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Methylprednisolone	C	Unknown		Not Reported
	Metoprolol	C	Unknown		Not Reported
	Pantoloc	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Slow-K	C	Unknown		Not Reported
	Ventolin	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248304	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SF11801		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Off Label Use; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral	Rosuvastatin		Astrazeneca
	Rosuvastatin Calcium			S	Oral	Rosuvastatin		Astrazeneca
	Rosuvastatin Calcium			S	Oral	Rosuvastatin		Astrazeneca
	Rosuvastatin Calcium			S	Oral	Rosuvastatin		Astrazeneca
	Actemra			S	Unknown			Not Reported
	Apo Azathioprine			S	Unknown			Not Reported
	Apo Azathioprine			S	Unknown	Azathioprine		Not Reported
	Apo Azathioprine			S	Unknown	Azathioprine		Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral	20.0mg Unknown	Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Allopurinol	C	Unknown		Not Reported
	Cephalexin Monohydrate	C	Oral		Not Reported
	Coversyl	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248548	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2020035122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister;	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Adalimumab			S				Not Reported
	Arava			S	Oral	20 Milligram		Not Reported

Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate [Methotrexate Sodium]	S	Oral	20 Milligram	Not Reported
	Methotrexate [Methotrexate Sodium]	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S			Not Reported
	Tofacitinib	S		10 Milligram	Not Reported
	Xeljanz	S		10 Milligram	Not Reported
	Alendronate Acid (Alendronate Acid)	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Paracetamol	C			Not Reported
	Caffeine Citrate	C			Not Reported
	Codeine Phosphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248873	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE HUNGARY KFT-2020CA025777			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	10.0 Milligram		Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248876	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025719			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50.0 Milligram, 1 Every 1 Weeks	Not Reported
	Etanercept	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40.0 Milligram, 2 Every 1 Days	Not Reported
	Humira	S	Subcutaneous	40.0 Gram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	2000.0 Milligram	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Other		Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	750 Milligram, 1 Every 1 Weeks	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	5.0 Milligram, 1 Every 2 Weeks	Not Reported
	Tofacitinib	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248909	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025752			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2 Every 1 Day		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Subcutaneous			Not Reported
	Erythromycin			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Oral	17.5 Mg, 1 Every 1 Week		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral	22.5 Mg 1 Every 1 Week		Not Reported
	Methotrexate			S				Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Orencia			S	Unknown	1000 Mg		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Wellbutrin			S	Unknown	300 Mg, 1 Every 1 Day		Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Day		Not Reported

	Bupropion	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Celebrex	C	Unknown	200 Mg, 2 Every 1 Day	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	4000 Iu (International Unit), 1 Every 1 Day	Not Reported
	Risedronate	C	Oral	35 Mg, 1 Every 1 Week	Not Reported
	Risedronate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248914	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025746			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248923	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025753			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Unknown	4 Mg/Kg		Not Reported
	Arava			S	Oral	10 Mg, 1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Months		Not Reported
	Plaquenil			S	Oral	200 Mg, 2 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Mg, 1 Every 1 Months		Not Reported
	Prednisone			C				Not Reported
	Prevacid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248934	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025738			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Days	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, 2 Every 1 Days	Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248939	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025741			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hypertension; Off Label Use; Therapeutic Product Effect Decreased	Rituximab (Unknown)	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1 Every 1 Days	Not Reported
	Methotrexate	S	Unknown	25 Mg, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cortisone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Hydromorphone	C	Unknown	1 Mg	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	400 Mg, 1 Every 1 Days	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	1 Mg	Not Reported
	Prednisone	C	Unknown	5 Mg, 1 Every 1 Days	Not Reported
	Valsartan	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248956	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA025735			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Rituximab (Unknown)			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18248992	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025761			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Amlodipine Besilate			S	Oral	1 Every 1 Days		Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Amlodipine Besilate			S	Oral	5 Milligram, 1 Every 1 Days		Not Reported
	Asacol			S	Unknown	800 Milligram, 3 Every 1 Days		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Atacand Plus			C	Unknown			Not Reported

Bisoprolol Fumarate	C	Unknown			Not Reported
Depo-Medrol	C	Intra-articular			Not Reported
Diphenhydramine	C	Oral	50 Milligram		Not Reported
Ebastine	C	Unknown			Not Reported
Ferrous Gluconate	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown			Not Reported
Vitamin D3	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18249111	EXPEDITED (15-DAY)		OT	CA-ROCHE-2673908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Intentional Product Use Issue; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18249302	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1824499		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Tachyarrhythmia; Tachycardia; Vomiting; Weight Decreased	Azithromycin			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18249702	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	4 Milligram		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S				Not Reported

Xeljanz	S			Not Reported
Alendronate Acid (Alendronate Acid)	S	Oral		Not Reported
Cortisone Acetate	S		25 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Subcutaneous		Not Reported
Desoximetasone	S			Not Reported
Diclofenac Sodium	S			Not Reported
Diclofenac	S			Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S			Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18249794	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SF11549		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Increased; Bronchitis; Cardiac Disorder; Contusion; Croup Infectious; Drug Ineffective; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased; Hypertension; Hypotension; Immunosuppression; Influenza; Infusion Related Reaction; Musculoskeletal Stiffness; Nasopharyngitis; Oropharyngeal Pain; Pain; Pertussis; Productive Cough; Stress; Unevaluable Event; Weight Decreased; Weight Increased	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Humalog	C	Unknown	Not Reported
	Sertraline Hydrochloride	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18277907	DIRECT					30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S				Not Reported
	Levofloxacin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18277911	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Abnormal; Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S				Not Reported
	Darunavir-Cobicstat			S				Not Reported
	Colchicine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18277993	DIRECT		DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Death; Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S				Not Reported
	Lopinavir-Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18278046	DIRECT		DE			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Coagulopathy; Foetal Exposure During Pregnancy; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Product Use Issue; Septic Shock; Suspected Covid-19	Hydroxychloroquine			S				Not Reported
	Oseltamivir			S				Not Reported
	Lopinavir-Ritonavir			S				Not Reported
	Immunoglobulins, Intravenous			S	Intravenous (not otherwise specified)		3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18281687	DIRECT		OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Nausea; Off Label Use; Vomiting	Lopinavir-Ritonavir			S		Other Dose:400mg/100mg;	2 DAY	Not Reported
	Hydroxychloroquine			S			4 DAY	Not Reported
	Ceftriaxone			S			4 DAY	Not Reported
	Darunavir-Cobicstat			S		Other Dose:800mg/150mg;	2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18282567	DIRECT		DE			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypoxia; Off Label Use; Premature Baby	Hydroxychloroquine			S				Not Reported
	Oseltamivir			S				Not Reported
	Lopinavir-Ritonavir			S				Not Reported
	Immunoglobulins, Intravenous			S	Intravenous (not otherwise specified)		3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	13420223	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1056		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Lung Disorder; Skin Lesion; Therapeutic Product Effect Incomplete; Total Lung Capacity Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	5 Days Per Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	15108403	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; No Adverse Event; Rheumatoid Arthritis; Treatment Failure	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Buccal			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran			S	Unknown			Not Reported

Leflunomide	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S		Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Apo-Hydroxyquine (Hydroxychloroquine Sulfate)	S	Unknown	Not Reported
Hyaluronidase (Human Recombinant)\Rituximab	S	Intravenous drip	Not Reported
Hyaluronidase (Human Recombinant)\Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Remicade (Infliximab)	S	Intravenous (not otherwise specified)	Not Reported
Remicade (Infliximab)	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Vaginal	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	15620611	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2018-CA-975882		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion;	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Prednisone			S	Oral	2 Dosage Forms Daily;		Actavis
	Prednisone			S	Oral	6 Milligram Daily;		Actavis
	Prednisone			S	Unknown	100 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Oral	2.6 Milligram Daily;		Actavis
	Prednisone			S	Oral	2.6 Milligram Daily;		Actavis
	Prednisone			S	Oral	6 Milligram Daily;		Actavis
	Prednisone			S	Oral	6 Milligram Daily;		Actavis
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Polyarthritis; Prescribed Underdose; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Underdose; Vomiting; Wheelchair User	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Other		Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported

Triamcinolone Hexacetonide	S	Subcutaneous		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Subcutaneous		Not Reported
Infliximab	S	Unknown		Not Reported
Gamastan S/D Medicinal Ingredient Also Know As Immuneglobulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate Tablets, Usp	S	Oral	5 Mg/Kg Daily;	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Unknown		Not Reported

	Prednisone	S	Oral	6 Milligram Daily;	Not Reported
	Prednisone	S	Unknown	2.6 Milligram Daily;	Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram Daily;	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg Daily;	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S	Oral	6 Milligram Daily;	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported
	Anakinra	S			Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Apo Prednisone Tab 5mg	S	Oral	6 Milligram Daily;	Not Reported
	Apo Prednisone Tab 5mg	S	Oral		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	15674128	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574075-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra		S	Unknown	Not Reported
	Bactrim		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	15801165	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Apo-Leflunomide		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	15934147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656830-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	16066206	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20190307277		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Combivent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported

	Lasix	S	Unknown	Not Reported
	Lipitor	S	Unknown	Not Reported
	Losec	S	Unknown	Not Reported
	Metformin	S	Unknown	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Serevent	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	16248273	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2761854-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	16536778	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071381		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product	Ciprofloxacin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported

Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Enalapril	S	Unknown	Teva
	Hydrochlorothiazide	S	Unknown	Ivax
	Hydrochlorothiazide	S	Unknown	Ivax
	Losartan	S	Unknown	Teva
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Subcutaneous	Barr
	Methotrexate	S	Subcutaneous	Barr
	Metoprolol Tartrate	S	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Teva
	Moxifloxacin Hydrochloride	S	Unknown	Teva
	Pantoprazole Magnesium	S	Unknown	Teva
	Penicillin G	S	Unknown	Teva
	Cefalexin	S	Unknown	Not Reported
	Cefalexin	S	Unknown	Not Reported
	Enalapril Maleate	S	Unknown	Teva
	Losartan	S	Unknown	Teva
	Arava	S	Unknown	Not Reported
	Biaxin	S	Unknown	Not Reported
	Biaxin	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Levaquin	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

Pariet	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Diazide [Gliclazide]	S	Unknown		Not Reported
Lopressor	S	Unknown		Not Reported
Tecta	S	Unknown		Not Reported
Xeljanz	S	Oral	100 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Isoniazid	S	Unknown		Not Reported
Cipro	S	Unknown		Not Reported
Penicillin G	S	Unknown		Not Reported
Penicillin G	S	Unknown		Not Reported
Avelox	S	Unknown		Not Reported
Hydrochlorothiazide	S	Unknown		Not Reported
Hydrochlorothiazide	S	Unknown		Not Reported
Penicillin Nos	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Moxifloxacin Hcl Sandoz	S	Unknown		Not Reported
Gliclazide	S	Unknown		Not Reported
Codeine	S	Unknown		Not Reported
Clindamycin	S	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Gold Injections	C			Not Reported
Hydroxychloroquine	C			Not Reported
Iron Sucrose	C	Unknown		Not Reported
Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported
Colchicine	C			Not Reported
Coversyl [Perindopril Erbumine]	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C			Not Reported
Levothyroxine Sodium	C			Not Reported
Ranitidine	C			Not Reported
Venofer	C			Not Reported

	Veltassa	C	Not Reported
	Atenolol Tablets, Bp	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	17420592	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0792		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Kineret			S	Unknown	100 Milligram		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Erelzi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18035799	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-034755			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Oral	5 Milligram, Two Times A Day (10 Milligram, Daily)		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day (10 Milligram, Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18133298	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1070709		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Function Test Abnormal; Off Label Use	Azithromycin			S	Oral	500mg Loading Dose And 250 Mg Q/24h Maintenance Dose		Mylan
	Azithromycin			S				Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg C/12h Dc Y 200mg C/12 Mant		Mylan
	Hidroxicloroquina /00072601/			S				Mylan

Dexametasona /00016001/	S	Intravenous (not otherwise specified)	6 Milligram, Qd (6mg C/24)	Mylan
Dexametasona /00016001/	S			Mylan
Ceftriaxona /00672201/	S	Intravenous (not otherwise specified)	2 Gram, Qd (2g/24h)	Mylan
Ceftriaxona /00672201/	S			Mylan
Remdesivir	S	Intravenous drip	100 Milligram, Qd (100 Mg C/24h)	Mylan
Remdesivir	S			Mylan
Midazolam	C		Unk	Mylan
Fentanilo /00174601/	C		Unk	Mylan
Enoxaparina	C		Unk	Mylan
Cisatracurio	C		Unk	Mylan
Paracetamol	C		Unk	Mylan
Omeprazol /00661201/	C		Unk	Mylan
Enalapril	C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18149719	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP015489		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Operation; Off Label Use; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Unevaluable Event; Urticaria	Apo-Leflunomide			S	Oral	10 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q.O.Wk.		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Q.O.Wk.		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Q.Wk.		Not Reported
Methotrexate	S				Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Amlodipine	C	Unknown	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	500 Milligram		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Viread	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18175720	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qd		Not Reported
Sulfasalazine	S	Oral	1 Gram, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18216075	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1821264		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Chorioretinitis; Macular Degeneration; Necrotising Retinitis; Vitritis	Mycophenolate			S	Unknown	3000 Milligram Daily;		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Prednisone			S	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18221891	EXPEDITED (15-DAY)		HO, LT, OT	TR-ACCORD-198956		28 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Electrocardiogram Qt Prolonged; Sinus Bradycardia; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	2 X 200 Mg		Not Reported
	Oseltamivir/Oseltamivir Phosphate			C	Oral	2 X 75 Mg		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18241999	EXPEDITED (15-DAY)		OT	IT-FRESENIUS KABI-FK202008942		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Levofloxacin (Manufacturer Unknown)			S	Unknown	500 Mg/Day		Fresenius Medical Care
	Ceftriaxon (Manufacturer Unknown)			S	Unknown	Unk		Not Reported
	Clarithromycin			S				Not Reported

Hydroxychloroquine Sulfate	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18244122	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202008008374			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Encephalopathy; Fall; Hypercapnia; Hypoxia; Lung Opacity; Muscle Injury; Muscular Weakness; Myopathy Toxic; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Subarachnoid Haemorrhage; Tibia Fracture; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydrocortisone Salt Not Specified			S	Unknown	30 Mg, Qd (20 Mg Every Morning And 10 Mg In The Afternoon)		Not Reported
	Anakinra			C	Subcutaneous	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250029	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05702		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Aspirin [Acetylsalicylic Acid]			S	Unknown	Low Dose		Not Reported
	Aspirin [Acetylsalicylic Acid]			S				Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250135	EXPEDITED (15-DAY)		OT	NVSC2020US247044		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Torsade De Pointes	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	400 Mg, Bid Loading Dose		Not Reported
	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250415	EXPEDITED (15-DAY)		LT, OT	RU-LUPIN PHARMACEUTICALS INC.-2020-05642		44 YR	Male	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibrin D Dimer Increased; Lymphocyte Count Increased; Neutrophilia; Off Label Use	Methylprednisolone			S	Unknown	1000 Milligram, Pulse Therapy		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Dexamethasone			S	Unknown	8 Milligram, Unk		Not Reported
	Bromhexine			S	Unknown	8 Milligram, Unk		Not Reported
	Imidazolyl Ethanamide Pentandioic Acid			S	Unknown	Unk		Not Reported
	Enoxaparin Sodium			C	Unknown	40 Milligram, Unk		Not Reported
	Enoxaparin Sodium			C	Unknown	80 Milligram, Unk		Not Reported
	Spironolactone			C	Unknown	50 Milligram, Unk		Not Reported
	Colchicine			C	Unknown	1 Milligram, Unk		Not Reported
	Colchicine			C	Unknown	0.5 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250615	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-047045		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250647	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1825599		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250649	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825534		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Hypoaesthesia; Joint Swelling; Muscular Weakness; Nerve Injury; Off Label Use; Pain; Product Use Issue; Sciatica; Spinal Stenosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel Xr			C	Unknown			Not Reported
	Baclofen			C	Unknown			Not Reported

	Folic Acid	C	Unknown	5 Milligram Daily;	Not Reported
	Lyrica	C	Unknown	75 Milligram Daily;	Not Reported
	Prednisone	C	Oral	7.5 Milligram Daily;	Not Reported
	Vitamin D	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250698	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05672		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Nitazoxanide			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250815	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825330			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Infection; Leukopenia; Lymphopenia; Rash; Rash; Serum Ferritin Increased; Systemic Lupus Erythematosus; Transient Ischaemic Attack; Treatment Failure; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Atorvastatin Calcium			C				Not Reported
	Bisoprolol			C				Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Mycophenolate Sodium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18250959	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825668			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Drug Intolerance; Orthostatic Hypotension; Palmoplantar Pustulosis; Presyncope; Rash; Red Blood Cell Sedimentation Rate Increased; Retinopathy	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251047	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825335			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			C				Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251086	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05670		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (On Day 1)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (On		Lupin

				Days 2-5)	
	Azithromycin	S	Unknown	500 Milligram, On Day 1	Lupin
	Azithromycin	S	Unknown	250 Milligram, On Days 2-5	Lupin
	Methylprednisolone	S	Unknown	40 Milligram, Bid (On Days 1-3)	Lupin
	Nitric Oxide	S	Unknown	Unk (Stopped)	Not Reported
	Anakinra	S	Unknown	100 Milligram, Every 6 Hours On Days 1-5	Not Reported
	Anakinra	S	Unknown	100 Milligram, Bid On Days 5-10	Not Reported
	Anakinra	S	Unknown	100 Milligram, Qd, On Days 11-13	Not Reported
	Remdesivir	C	Unknown	200 Milligram, On Day 1	Not Reported
	Remdesivir	C	Unknown	100 Milligram, Qd, Days 2-5	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251255	EXPEDITED (15-DAY)		OT	CA-ROCHE-2673689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Intravenous drip			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251373	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05703		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Aspirin [Acetylsalicylic Acid]			S	Unknown	Low Dose		Not Reported
	Aspirin [Acetylsalicylic Acid]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251400	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05701		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Normal Newborn; Premature Delivery; Premature Rupture Of Membranes	Hydroxychloroquine			S	Unknown	At The Time Of Conception		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd (After Confirmation Of		Lupin

					Pregnancy)	
	Aspirin [Acetylsalicylic Acid]		S	Unknown	100 Milligram, Qd (Low Dose)	Not Reported
	Aspirin [Acetylsalicylic Acid]		S			Not Reported
	Immunoglobulins Nos		S	Intravenous (not otherwise specified)	400 Milligram/Kilogram, Monthly	Not Reported
	Immunoglobulins Nos		S			Not Reported
	Low Molecular Weight Heparin		S	Unknown	4000 International Unit, Qd	Not Reported
	Low Molecular Weight Heparin		S			Not Reported
	Insulin		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251419	EXPEDITED (15-DAY)		DE, HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-05696		64 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Penicillium Infection; Pleural Effusion; Pneumonia Fungal	Methylprednisolone			S	Unknown	24 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Lupin
	Cyclosporine			S	Unknown	50 Milligram, Bid		Not Reported
	Sodium Bicarbonate			C	Unknown	0.5 Gram, Tid		Not Reported
	Febuxostat			C	Unknown	40 Milligram, Qd		Not Reported
	Amlodipine			C	Unknown	5 Milligram, Qd		Not Reported
	Torasemide			C	Unknown	10 Milligram, Qd		Not Reported
	Warfarin			C	Unknown	2.5 Milligram, Qd		Not Reported
	Potassium Chloride			C	Unknown	0.5 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251435	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825949		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Ergocalciferol	C			Not Reported
	Folinic Acid	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251437	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825551			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251473	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020180671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline

Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cortisone Acetate	S	Unknown	25 Milligram	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Cortison	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Paracetamol + Codeine Phosphate	C	Unknown	Unk	Glaxosmithkline
	Leflunomide	C	Unknown	Unk	Not Reported

	Caffeine Citrate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251506	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05705		35 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Normal Newborn; Premature Delivery; Premature Rupture Of Membranes	Hydroxychloroquine			S	Unknown	At The Time Of Conception		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Aspirin [Acetylsalicylic Acid]			S	Unknown	Low Dose		Not Reported
	Aspirin [Acetylsalicylic Acid]			S				Not Reported
	Prednisone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Prednisone			S				Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	400 Milligram/Kilogram, Monthly		Not Reported
	Immunoglobulins Nos			S				Not Reported
	Low Molecular Weight Heparin			S	Unknown	4000 International Unit, Qd		Not Reported
	Low Molecular Weight Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251526	EXPEDITED (15-DAY)		DE, HO, LT	DE-TEVA-2020-DE-1825057		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Cardiac Arrest; Cardiogenic Shock; Cardiomyopathy; Cardiopulmonary Failure; Electrocardiogram Qt Prolonged; Left Ventricular Failure; Pleural Effusion; Pulmonary Congestion; Respiratory Failure	Hydroxychloroquine			S	Unknown	400 Milligram Daily; 200 Mg 1-0-1 For 4 Years, Previously For 5 Years 1-0- 0, Cumulative Dose About		Teva
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Teva
	Torasemide			C	Unknown	20 Milligram Daily; 20 Mg 1-0-0		Not Reported
	Vitamin D			C	Unknown			Not Reported
	Allopurinol			C	Unknown	100 Milligram Daily; 100		Not Reported

				Mg 0-0-1	
	L-Thyroxine	C	Unknown	75 Microgram Daily; 75 Microg 1-0-0	Not Reported
	Tilidine/Naloxone	C	Unknown	150/12 Mg 1-0-1	Not Reported
	Metamizole	C	Unknown	1500 Milligram Daily; 500 Mg 1-1-1	Not Reported
	Ibandronic Acid	C	Unknown	50 Mg 3 Times A Week	Not Reported
	Ciprofloxacin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251560	EXPEDITED (15-DAY)		OT	NVSC2020CA241066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Epigastric Discomfort; Gastric Ulcer Perforation; General Physical Health Deterioration; Hypertension	Diclofenac			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Voltaren			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cortisone			C	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251664	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05773			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	200 Milligram, Qd		Lupin
	Aspirine			S	Transplacental	100 Milligram, Qd (Low		Not Reported

				Dose)	
	Aspirine	S			Not Reported
	Cyclophosphamide	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	5 Milligram, Qd	Not Reported
	Prednisone	S			Not Reported
	Warfarin	S	Transplacental	Unk	Not Reported
	Immunoglobulins Nos	S	Intravenous (not otherwise specified)	400 Milligram/Kilogram,Monthly	Not Reported
	Immunoglobulins Nos	S			Not Reported
	Low Molecular Weight Heparin	S	Transplacental	4000 International Unit, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251665	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05697		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Normal Newborn; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Aspirine			S	Unknown	100 Milligram, Qd (Low Dose)		Not Reported
	Aspirine			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			S				Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	400 Milligram/Kilogram,Monthly		Not Reported
	Immunoglobulins Nos			S				Not Reported
	Low Molecular Weight Heparin			S	Unknown	4000 International Unit, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251667	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05698		30 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Aspirin [Acetylsalicylic Acid]			S	Unknown	Unk,Low Dose		Not Reported
	Aspirin [Acetylsalicylic Acid]			S				Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251668	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05774			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	200 Milligram, Qd		Lupin
	Aspirine			S	Transplacental	100 Milligram, Qd (Low Dose)		Not Reported
	Aspirine			S				Not Reported
	Cyclophosphamide			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	5 Milligram, Qd		Not Reported
	Prednisone			S				Not Reported
	Warfarin			S	Transplacental	Unk		Not Reported
	Immunoglobulins Nos			S	Transplacental	400 Milligram/Kilogram,Monthly		Not Reported
	Immunoglobulins Nos			S				Not Reported
	Low Molecular Weight Heparin			S	Transplacental	4000 International Unit, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251683	EXPEDITED (15-DAY)		OT	CA-ACCORD-200019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Psoriasis	Methotrexate			S				Accord
	Cosentyx			S				Not Reported
	Enbrel			S				Not Reported
	Plaquenil			S				Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251718	EXPEDITED (15-DAY)		HO, LT, OT	US-TORRENT-00010389			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Embolic Stroke; Encephalomalacia; Encephalopathy; Fall; Hypercapnia; Muscle Injury; Myopathy; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Subarachnoid Haemorrhage; Tibia Fracture; Toxicity To Various Agents	Hydroxychloroquine			S				Unknown
	Hydrocortisone			S		Every Morning		Not Reported
	Anakinra			C	Subcutaneous			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251771	EXPEDITED (15-DAY)		OT	CA-ACCORD-199948		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate			S	Subcutaneous			Accord

Rheumatoid Arthritis	Certolizumab Pegol	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Etanercept	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	2 Every 1 Days		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab/Vorhyaluronidase Alfa	S	Subcutaneous			Not Reported
	Xeljanz	C				Not Reported
	Methotrexate	S	Oral			Accord
	Hydroxychloroquine	S	Unknown	2 Every 1 Days		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251818	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05789			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Hydroxychloroquine			S	Transplacental	At The Time Of Conception		Lupin
	Hydroxychloroquine			S	Transplacental	200 Milligram, Qd (After Confirmation Of Pregnancy)		Lupin
	Aspirin [Acetylsalicylic Acid]			S	Transplacental	100 Milligram, Qd (Low Dose)		Not Reported
	Aspirin [Acetylsalicylic Acid]			S				Not Reported
	Immunoglobulins Nos			S	Transplacental	400 Milligram/Kilogram, Monthly		Not Reported
	Immunoglobulins Nos			S				Not Reported
	Low Molecular Weight Heparin			S	Transplacental	4000 International Unit, Qd		Not Reported
	Low Molecular Weight Heparin			S				Not Reported
	Insulin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251840	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05793			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	At The Time Of Conception		Lupin
	Hydroxychloroquine			S	Transplacental	200 Milligram, Qd		Lupin
	Aspirin [Acetylsalicylic Acid]			S	Transplacental	Low Dose		Not Reported
	Aspirin [Acetylsalicylic Acid]			S				Not Reported
	Prednisone			S	Transplacental	7.5 Milligram, Qd		Not Reported
	Prednisone			S				Not Reported
	Immunoglobulins Nos			S	Transplacental	400 Milligram/Kilogram, Monthly		Not Reported
	Immunoglobulins Nos			S				Not Reported
	Low Molecular Weight Heparin			S	Transplacental	4000 International Unit, Qd		Not Reported
	Low Molecular Weight Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251963	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825685		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen/Codeine Phosphate			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported

	Cimzia	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported
	Rabeprazole	C	Unknown	Not Reported
	Remicade	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252434	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259763		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis	Hydroxychloroquine			S	Unknown	Only One Dose Of 400 Mg		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252438	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05699		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Aspirin [Acetylsalicylic Acid]			S	Unknown	Low Dose		Not Reported
	Aspirin [Acetylsalicylic Acid]			S				Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252460	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05700		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Exposure During Pregnancy	Hydroxychloroquine	S	Unknown	Unk		Lupin
	Hydroxychloroquine	S				Lupin
	Aspirin [Acetylsalicylic Acid]	S	Unknown	Low Dose		Not Reported
	Aspirin [Acetylsalicylic Acid]	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252516	EXPEDITED (15-DAY)		OT	CA-ACCORD-199991		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Accord
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Prednisone			C	Oral			Not Reported
	Lyrica			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252565	EXPEDITED (15-DAY)		OT	CA-ACCORD-200016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis;	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Stomatitis; Swelling			otherwise specified)		
	Humira	S	Subcutaneous	Subcutaneous Solution	Not Reported
	Aurothioglucose	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Sulfasalazine	C			Not Reported
	Methotrexate	S	Unknown		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252572	EXPEDITED (15-DAY)		OT	CA-ACCORD-199795		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Oral	1 Every 1 Weeks, Not Specified		Accord
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown	Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Minocycline	C	Unknown	Not Specified		Not Reported
Azathioprine	C	Unknown	Not Specified		Not Reported
Penicillamine	C	Unknown	Not Specified		Not Reported
Prednisone	C	Unknown	Not Specified		Not Reported
Ciclosporin	C	Unknown	Not Specified		Not Reported
Actemra	C	Unknown	Not Specified		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate	S	Parenteral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18253025	EXPEDITED (15-DAY)		HO, OT	JP-IPCA LABORATORIES LIMITED-IPC-2020-JP-002972			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Circulatory Collapse; Grunting; Hypokalaemia; Intentional Overdose; Moaning; Muscular Weakness; Paraesthesia; Poisoning; Toxicity To Various Agents; Vomiting	Hydroxychloroquine			S	Unknown	10 Gram		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18253094	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181471			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride +			S	Unknown	Unk		Glaxosmithkline

Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cortisone Acetate	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Unknown	50 Milligram	Glaxosmithkline
	Diclofenac	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Subcutaneous	400 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Alendronate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S			

	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18253278	EXPEDITED (15-DAY)		OT	CA-ACCORD-199992		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Off Label Use; Rheumatoid Arthritis	Methotrexate			S				Accord
	Orencia			S				Not Reported
	Arava			S				Not Reported
	Lyrica			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S				Not Reported
	Wellbutrin			C		1 Every 1 Days		Not Reported
	Valsartan			C		1 Every 1 Days		Not Reported
	Tylenol			C				Not Reported
	Trazodone			C		1 Every 1 Days		Not Reported
	Pseudoephedrine			C		1 Every 1 Days		Not Reported
	Sulfasalazine			C		2 Every 1 Days		Not Reported
	Nexium			C		1 Every 1 Days		Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			C		1 Every 1 Days		Not Reported
	Bimatoprost			C	Ophthalmic	1 Every 1 Days		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18253709	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Folic Acid			S	Oral	25 Mg		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline
	Cimzia (Certolizumab Pegol)			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	4 Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sarilumab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Alendronic Acid	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18254308	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1076448		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hypertransaminasaemia; Off Label Use	Azithromycin			S		500 Milligram, Qd		Mylan
	Hidroxicloroquina /00072601/			S		200 Milligram, Qod		Mylan
	Enoxaparina			C	Subcutaneous	Unk		Mylan
	Omeprazol /00661201/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18254335	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181545			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride +			S	Unknown	Unk		Glaxosmithkline

Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Pseudoephedrine Hydrochloride	S	Topical	25 Milligram		Glaxosmithkline
	Cortisone Acetate	S	Oral	Unk		Glaxosmithkline
	Desoximetasone	S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium	S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid	S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Subcutaneous	Unk		Not Reported
	Cimzia	S	Oral	Unk		Not Reported
	Arava	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	40 Milligram		Not Reported
	Humira	S	Intra-arterial	25 Milligram		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Simponi	S	Oral	Unk		Not Reported
	Alendronate Sodium	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	500 Milligram		Not Reported
	Prednisone	S	Subcutaneous	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	Unk		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18254401	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1076676		49 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Diarrhoea; Lymphadenitis Bacterial; Off Label Use; Rhabdomyolysis; Transaminases Increased	Lopinavir/Ritonavir Mylan			S	Oral	4 Dosage Form, Qd (2cp 12/12h)		Mylan
	Plaquinol			S	Oral	D1 400mg 12/12h, D2 E Seguintes 200mg 12/12h		Mylan
	Enoxaparin Sodium			C		Unk		Mylan
	Acetylcysteine			C		Unk		Mylan
	Esomeprazole			C		Unk		Mylan
	Levetiracetam			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18254562	EXPEDITED (15-DAY)		DS, LT, OT	CA-GLAXOSMITHKLINE-CA2020181672			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Cutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported

Issue; Joint Swelling; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate	S	Oral	25 Milligram		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Subcutaneous	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Unknown	Unk		Not Reported
	Tofacitinib	S	Unknown	10 Milligram		Not Reported
	Xeljanz	S	Unknown	10 Milligram		Not Reported
	Alendronate Sodium	S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram		Not Reported
	Paracetamol	C	Unknown	Unk		Glaxosmithkline
	Codeine Phosphate	C	Unknown	Unk		Glaxosmithkline
	Caffeine Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18282106	DIRECT		DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Multiple Organ Dysfunction Syndrome; Off Label Use	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Other Frequency:2 Doses;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18282113	DIRECT					80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Lung Consolidation;	Lopinavir-Ritonavir	S	Not Reported
Product Use Issue;	Hydroxychloroquine	S	Not Reported
Pyrexia; Respiratory Gas Exchange Disorder	Tocilizumab	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18282529	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Sars-Cov-2 Test Positive	Hydroxychloroquine			S			5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	15705980	EXPEDITED (15-DAY)		OT	CA-009507513-1812CAN000060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Fosamax			S	Unknown	Dosage Form: Not Specified		Merck
	Vasotec			S	Unknown	Dosage Form: Not Specified		Merck
	Vasotec			S	Unknown	Dosage Form: Not Specified		Merck
	Cozaar			S	Unknown	Unk		Merck
	Cozaar			S	Unknown	Unk		Merck
	Enalapril Maleate			S	Unknown	Unk		Merck
	Enalapril Maleate			S	Unknown	Unk		Merck
	Enalapril Maleate			S	Unknown	Unk		Merck
	Losartan Potassium			S	Unknown	Unk		Merck
	Losartan Potassium			S	Unknown	Unk		Merck
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Celebrex	S	Unknown	Unk	Not Reported
Ciprofloxacin	S	Unknown	Unk	Not Reported
Ciprofloxacin	S	Unknown	Unk	Not Reported
Clindamycin	S	Unknown	Unk, Unknown	Not Reported
Clindamycin	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Week	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Week	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Hydralazine Hydrochloride	S	Unknown	Dosage Form: Not Specified	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Dosage Form: Not Specified	Not Reported
Levaquin	S	Unknown	Dosage Form: Not Specified	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week, Dosage Form: Not Specified	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Unknown	Dosage Form: Not Specified	Not Reported
Metoprolol Tartrate	S	Unknown	Dosage Form: Not Specified	Not Reported
Moxifloxacin Hydrochloride	S	Unknown	Dosage Form: Not Specified	Not Reported
Pantoprazole Magnesium	S	Unknown	Unk	Not Reported

Pariet	S	Unknown	Dosage Form: Tablet (Enteric-Coated)	Not Reported
Penicillin G	S	Unknown	Unk	Not Reported
Penicillin G	S	Unknown	Dosage Form: Not Specified	Not Reported
Keflex	S	Unknown	Unk, Unknown	Not Reported
Keflex	S	Unknown	Dosage Form: Not Specified	Not Reported
Penicillin (Unspecified)	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Diazide (Gliclazide)	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Dosage Form: Not Specified	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S	Unknown	50 Milligram, 2 Every 1 Day(S)	Not Reported
Lopressor	S	Unknown	Dosage Form: Not Specified	Not Reported
Tecta	S	Unknown	Dosage Form: Tablet (Enteric-Coated)	Not Reported
Clindamycin Phosphate	S	Unknown		Not Reported
Cipro (Ciprofloxacin)	S	Unknown	Unk	Not Reported
Cipro (Ciprofloxacin)	S	Unknown	Unk	Not Reported
Cipro (Ciprofloxacin)	S	Unknown	Unk	Not Reported
Cipro (Ciprofloxacin)	S	Unknown	Unk	Not Reported
Clindamycin Hydrochloride	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Dosage Form: Not	Not Reported

				Specified	
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Dosage Form: Not Specified	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, 1 Every 1 Day	Not Reported
	Prednisone	C	Unknown	Dosage Form: Not Specified	Not Reported
	Venofer	C	Unknown	Unk, Intravenous Solution	Not Reported
	Venofer	C	Unknown	Dosage Form: Solution Intravenous	Not Reported
	Atenolol	C	Unknown	Unk	Not Reported
	Colchicine	C	Unknown	Unk	Not Reported
	Coversyl (Perindopril Erbumine)	C	Unknown	Unk	Not Reported
	Leucovorin	C	Unknown	Dosage Form: Not Specified	Not Reported
	Levothyroxine Sodium	C	Unknown	Unk	Not Reported
	Ranitidine	C	Unknown	Dosage Form: Not Specified	Not Reported
	Veltassa	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	15940125	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2657252-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Decreased	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Meloxicam	C	Oral	Not Reported
	Prednisolone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	16424275	EXPEDITED (15-DAY)		HO	US-ABBVIE-19K-163-2816101-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Heart Valve Incompetence; Musculoskeletal Stiffness; Pain; Pleural Effusion; Sensitivity To Weather Change	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Digoxin			C		125 Mcg		Not Reported
	Furosemide			C		Powder		Not Reported

	Metoprolol Succinate	C	Tablet 2; 100 Mg	Not Reported
	Chlorthalidone	C	25 Mg	Not Reported
	Atenolol	C	25 Mg	Not Reported
	Gabapentin	C	300 Mg	Not Reported
	Hydroxychloroquine	C	200 Mg	Not Reported
	Lovastatin	C	40 Mg	Not Reported
	Voltaren	C		Not Reported
	Metoprolol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	16783894	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2018SP010306			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Tacrolimus			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Betamethasone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	16783925	NON-EXPEDITED		HO, OT	US-STRIDES ARCOLAB LIMITED-2018SP010304		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	Unk		Strides
	Tacrolimus			S	Transplacental	Unk		Strides
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	16902124	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2019AMR181621			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Live Birth	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S	Intravenous (not otherwise specified)	600 Mg, Q4wks		Glaxosmithkline
	Calcium Unknown			S	Oral	1000 Mg, 1d		Glaxosmithkline
	Levothyroxine			S	Oral	88 ?G, 1d		Glaxosmithkline
	Triamcinolone			S	Topical	Unk Unk, Bid Prn		Glaxosmithkline
	Vitamin D3			S	Oral	1000 Df, Bid		Glaxosmithkline
	Alprazolam			S	Oral	Unk, Prn		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Zoloft			S	Oral	1.5 Df, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17241794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510421		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	5.0 Years		Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported

Arthritis; Somnolence; Visual Impairment	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Codeine Phosphate	C		Not Reported
	Hydromorph	C		Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C		Not Reported
	Synthroid	C		Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported
	Hydromorphone Hcl	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17545125	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2020M1026414			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaemia; Arthralgia; Dermal Cyst; Dry Mouth; Fall; Lower Limb Fracture; Nasopharyngitis; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Methotrexate			S	Unknown	5 Mg, Unk		Mylan
	Methotrexate			S	Unknown	7.5 Mg, Unk		Mylan
	Methotrexate			S	Unknown	2.5 Mg, Unk		Mylan
	Methotrexate			S	Unknown	5 Mg, Unk		Mylan
	Methotrexate			S	Unknown	2.5 Mg, Unk		Mylan

Methotrexate	S	Unknown	7.5 Mg, Unk		Mylan
Mabthera	S	Unknown	500 Mg, Unk		Mylan
Mabthera	S	Unknown	500 Mg, Unk		Mylan
Mabthera	S	Unknown	500 Mg, Unk		Mylan
Hydroxychloroquine	S	Unknown	400 Mg, Unk		Mylan
Hydroxychloroquine	S	Unknown	400 Mg, Qd		Mylan
Rixathon	S	Unknown	500 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17726709	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004067			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Off Label Use; Septic Shock; Sinus Tachycardia; Sinus Tachycardia	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17823242	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1051022		25 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash	Azithromycin			S	Oral	500 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	200 Milligram, Qd		Mylan
	Augmentin /00852501/			S	Oral	1 Gram, Qd		Mylan
	Clexane			C	Subcutaneous	1 Dosage Form, Qd		Mylan
	Dicloreum /00372301/			C	Intramuscular	1 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17846599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605656		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Actemra	S	Unknown	Not Reported
	Allopurinol	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported
	Amitriptyline Hydrochloride;Perphenazine	S	Unknown	Not Reported
	Apo-Amitriptyline	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Diclofenac	S	Topical	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S		Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S		Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Parenteral	Not Reported

	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Misoprostol	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Winpred	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17884744	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1247025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain	Methotrexate			S	Subcutaneous			Barr
	Boric Acid			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Edta (Disodium Edetate)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Gold Injections	S	Unknown		Not Reported
	Humira (Adalimumab)	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phenylephrine Hydrochloride Injection Usp	S	Unknown		Not Reported
	Rho D Immune Globulin	S	Unknown		Not Reported
	Rituximab Gp2013	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Sodium Perborate	S	Unknown		Not Reported
	Celebrex	C			Not Reported
	Ibuprofen	C			Not Reported
	Lipitor	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17956170	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-185903		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated;	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Prednisone	S	Unknown		Not Reported
	Metaraminol	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone	S	Topical		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Subcutaneous	1 Every 1 Days	Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral	1 Every 1 Days	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported

Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S		1 Every 1 Days	Not Reported
Sulfathalidine	S	Subcutaneous		Not Reported
Hydrocortisone	S	Oral		Not Reported
Hydrocortisone	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Reactine [Cetirizine]	S			Not Reported
Sulfasalazine	C	Unknown		Not Reported
Tofacitinib	C	Unknown		Not Reported
Atasol	C	Unknown		Not Reported
Leflunomide	C			Not Reported
Folic Acid	S	Oral		Not Reported
Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
Methotrexate	S	Oral	1 Every 1 Days	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Intra-arterial		Not Reported
Sulfasalazine	S		1 Every 1 Days	Not Reported
Actemra	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Plaquenil	S	Oral	1 Every 1 Days	Not Reported
Metaraminol	S	Oral		Not Reported
Hydroxychloroquine	S			Not Reported
Plaquenil	S	Oral	1 Every 1 Days	Not Reported
Sulfasalazine	S	Subcutaneous	1 Every 1 Days	Not Reported
Desoximetasone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	17959570	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2020-031289		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Citalopram			S	Unknown	Unk		Aurobindo
	Fenofibrate			S	Unknown	Unk		Aurobindo
	Furosemide			S	Unknown	Unk		Aurobindo
	Hydrocodone Bitartrate And Acetaminophen			S	Unknown	Unk		Aurobindo
	Lisinopril			S	Unknown	Unk		Aurobindo
	Trazodone			S	Unknown	Unk		Aurobindo
	Xtandi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported
	Perforomist			S	Unknown	Unk		Not Reported
	Doxycycline Hyclate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	1 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18006319	EXPEDITED (15-DAY)		HO, OT	PR-ABBVIE-20K-131-3473440-00			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Blindness; Bone Marrow Transplant; Cardiac Failure; Covid-19; Decreased Appetite; Decreased Appetite; Dehydration; Dental Caries; Pathological Tooth	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Celebrex			C	Oral			Not Reported
	Nexium			C	Oral			Not Reported

Fracture; Pulmonary Hypertension; Red Blood Cell Sedimentation Rate Increased; Somnolence; Weight Decreased	Methotrexate		C	Oral	Not Reported
	Vitamin B12		C	Other	Not Reported
	Actonel		C	Oral	Not Reported
	Vitamin D3		C	Oral	Not Reported
	Folic Acid		C	Oral	Not Reported
	Omega 3-6-9		C	Oral	Not Reported
	Protect Plus So		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18031196	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056795		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin Calcium			S	Oral	5 Milligram, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18146660	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013321		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Apotex
	Hydroxychloroquine	S	Oral	400 Milligram	Apotex
	Apo-Leflunomide	S	Oral	10 Milligram, Qd	Apotex
	Naproxen	S	Unknown	Unk	Apotex
	Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S			Not Reported
	Methotrexate Sodium	S	Intramuscular	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk Unk, Q.M.T.	Not Reported
	Actemra	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk Unk, Qd	Not Reported
	Arava	S	Oral	10 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	20 Milligram, Q.Wk.	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Unk	Not Reported
	Lantus	C	Subcutaneous	Unk	Not Reported
	Lozide /00340101/	C	Unknown	Unk	Not Reported
	Metformin	C	Oral	Unk	Not Reported
	Naprosyn /00256201/	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Asa	C	Unknown	81 Mg, Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported

	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18158622	EXPEDITED (15-DAY)		DS	CA-ROCHE-2656511		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Confusional State; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis;	Actemra			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine			S				Not Reported
	Chlorhexidine			S	Topical			Not Reported
	Chlorhexidine			S	Unknown			Not Reported
	Chlorhexidine Gluconate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Not Reported
	Periogard	S	Buccal	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Topicort (Canada)	S	Cutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported

	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Tylenol	C		Not Reported
	Tylenol With Codeine	C		Not Reported
	Pantoloc	C		Not Reported
	Pantoprazole	C		Not Reported
	Salazopyrina	C		Not Reported
	Ibuprofen	C		Not Reported
	Atasol (Canada)	C		Not Reported
	Cetirizine	C		Not Reported
	Desogestrel;Ethinylestradiol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18161149	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1814314		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Hidroxicloroquina (2143a)			S	Oral	400 Mg C / 12h Dc And 200mg C / 12 Maint		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500mg Shock Dose And 250 Mg C / 24h Maintenance		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	6mg C/24		Not Reported
	Dexametasona (722a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Remdesivir (10009a)			S	Intravenous drip	100 Mg C/24h		Not Reported
	Remdesivir (10009a)			S				Not Reported
	Midazolam (2256a)			C				Not Reported
	Fentanilo (1543a)			C				Not Reported

Enoxaparina (2482a)	C		Not Reported
Cisatracurio (2738a)	C		Not Reported
Paracetamol (12a)	C		Not Reported
Omeprazol (2141a)	C		Not Reported
Enalapril (2142a)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18162895	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202008007822			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Oedema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Rinderon			C		1 Mg, Qd		Not Reported
	Rinderon			C		Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Bayaspirin			C		Unk		Not Reported
	Diart			C		Unk		Not Reported
	Spironolactone			C		Unk		Not Reported
	Mosapride Citrate			C		Unk		Not Reported
	Gabapen			C		Unk		Not Reported
	Miya Bm			C		Unk		Not Reported
	Selenica-R			C		Unk		Not Reported
	Amitiza			C		Unk		Not Reported
	Mystan			C		Unk		Not Reported
	Loxonin			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Fosamac			C		Unk		Not Reported
	Sennaride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18178685	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram		Apotex
	Apo-Leflunomide			S	Unknown	10 Milligram		Apotex
	Enbrel			S	Unknown	50 Milligram, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	5 Milligram		Not Reported
	Prednisone			C	Oral	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18189512	EXPEDITED (15-DAY)		OT	CA-009507513-2008CAN011101		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea;	Vasotec			S	Unknown	Dosage Form: Not Specified		Merck
	Vasotec			S	Unknown	Unk		Merck
	Cozaar			S	Unknown			Merck
	Cephalexin			S	Unknown	Dosage Form : Not Specified		Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram 1 Every 1 Weeks		Not Reported

Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Hydrochlorothiazide	S	Unknown		Not Reported
	Isoniazid	S	Unknown	Dosage Form: Not Specified	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	Dosage Form: Not Specified	Not Reported
	Metoprolol Tartrate	S	Unknown	Dosage Form: Not Specified	Not Reported
	Orencia	S	Unknown		Not Reported
	Penicillin G	S	Unknown	Dosage Form: Not Specified	Not Reported
	Xeljanz	S	Oral	50 Milligram, 2 Every 1 Days	Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Biaxin	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Clindamycin Hydrochloride	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Fosamax	S	Unknown		Merck
	Hydralazine Hydrochloride	S	Unknown		Not Reported
	Keflex	S	Unknown		Not Reported
	Levaquin	S	Unknown		Not Reported
	Metoprolol Tartrate	S	Unknown		Not Reported
	Moxifloxacin Hydrochloride	S	Unknown		Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Pariet	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Atenolol	C			Not Reported
	Colchicine	C			Not Reported

Coversyl (Perindopril Arginine)	C				Not Reported
Esomeprazole	C		Dosage Form: Not Specified		Not Reported
Leucovorin	C		Dosage Form: Not Specified		Not Reported
Levothyroxine Sodium	C		Dosage Form: Not Specified		Not Reported
Ranitidine	C		Dosage Form: Not Specified		Not Reported
Gold	C				Not Reported
Iron Sucrose	C				Not Reported
Prednisone	C	Unknown	8.5 Milligram, 1 Every 1 Days		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18196415	EXPEDITED (15-DAY)		OT	CA-ACCORD-197105		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate			S	Subcutaneous			Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Celebrex			S				Not Reported
	Arava			S				Not Reported
	Prednisone			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Methotrexate			S	Subcutaneous			Accord
	Methotrexate			S	Subcutaneous			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18238582	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1823617		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Azitromicina (7019a)			S		Unit Dose 500mg		Not Reported
	Hidroxicloroquina (2143a)			S		200mg		Teva
	Enoxaparina (2482a)			C	Subcutaneous			Not Reported
	Omeprazol (2141a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18240124	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020269934		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Back Pain; Depression; Drug Ineffective For Unapproved Indication; Fibromyalgia; Foot Deformity; Liver Function Test Increased; Migraine; Myofascial Pain Syndrome; Off Label Use; Osteoarthritis; Photosensitivity Reaction; Polyarthritis; Rheumatoid Arthritis; Road Traffic Accident; Systemic Lupus Erythematosus	Methotrexate Sodium			S		25 Mg		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Amitriptyline			C		10-20 Mg, Unk		Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			C		Unk (Tapered Off)		Not Reported
	Ferrous Fumarate			C		300 Mg, Daily		Not Reported
	Flexeril [Cefixime]			C		Unk		Not Reported
	Folic Acid			C		Unk, Daily		Not Reported
	Folic Acid			C		5 Mg, Daily (5/7 Days A Week)		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Imuran [Azathioprine]			C		50 Mg		Not Reported
	Omega 3 [Fish Oil]			C		Unk		Not Reported
	Oxycocet			C		Unk, As Needed		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	C	400 Mg, Daily, 6/7 Days A Week	Not Reported
	Leflunomide	C	20 Mg	Not Reported
	Leflunomide	C	10 Mg, Every Other Day	Not Reported
	Prednisone	C	5 Mg, Daily	Not Reported
	Ralivia	C	300 Mg, Daily	Not Reported
	Salazopyrin	C	2 G, Daily	Not Reported
	Temazepam	C	15 Mg, Daily	Not Reported
	Tiazac [Diltiazem Hydrochloride]	C	Unk	Not Reported
	Topamax	C	Unk	Not Reported
	Tramacet	C	2 Df, 2x/Day	Not Reported
	Vitamin D [Vitamin D Nos]	C	3000 Iu, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18254382	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-046978		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Artery Occlusion; Cerebrovascular Accident; Decompressive Craniectomy; Facial Paralysis; Hemiparesis; Off Label Use; Thrombectomy	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18254437	EXPEDITED (15-DAY)		HO	NL-SAMSUNG BIOEPIS-SB-2020-27926		57 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Etanercept			S	Unknown	1 Piece (S) Once A Week, Extra Info: 50mg Injvlst 50mg/Ml		Not Reported

	Sulfasalazine	S	Unknown	2 Times A Day 4 Piece (S), Extra Info: 500mg	Not Reported
	Methotrexaat	S	Unknown	1 Piece (S) Once A Week, Extra Info: 25mg / Wk	Not Reported
	Plaquenil	S	Unknown	1 Time Per Day 1 Piece (S), Extra Info: 200mg	Not Reported
	Plaquenil	S			Not Reported
	Bisoprolol	C	Unknown	1 Time Per Day 1 Piece (S), Extra Info: 10mg	Not Reported
	Lisinopril	C	Unknown	1 Time Per Day 1 Piece (S), Extra Info: 10mg	Not Reported
	Triamtereen/Hct	C	Unknown	1 Piece (S) Once A Day, Extra Info: 50/4	Not Reported
	Triamtereen/Hct	C	Unknown	1 Piece (S) Once A Day, Extra Info: 50/4	Not Reported
	Pantozol	C	Unknown	1 Piece (S) Once A Day, Extra Info: 40mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18254520	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05667		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Milligram, Qd		Lupin
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Novel Labs
	Cefepime			C	Unknown	Unk (Stopped)		Not Reported
	Tacrolimus			C	Unknown	5 Milligram, Bid		Not Reported
	Tacrolimus			C	Unknown	2.5 Milligram, Bid		Not Reported
	Mycophenolic Acid			C	Unknown	250 Milligram, Bid (Stopped)		Not Reported

	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18254587	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260538		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Nausea	Azithromycin			S	Unknown	Unk		Sun
	Ceftriaxona (501a)			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Hidroxicloroquina (2143a)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18254704	EXPEDITED (15-DAY)		OT	NZ-ADVANZ PHARMA-202009008493			Unknown	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Infection; Pulmonary Embolism; Rash	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18255082	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1825943			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18255708	EXPEDITED (15-DAY)		HO	CA-ACCORD-200113			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18255710	EXPEDITED (15-DAY)		OT	CA-ACCORD-200116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Subcutaneous			Accord
	Arava			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Minocycline			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Amoxicillin/Clavulanate			C				Not Reported

	Potassium Amoxil			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256072	EXPEDITED (15-DAY)		OT	CA-ACCORD-200109		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Accord
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256073	EXPEDITED (15-DAY)		OT	CA-ACCORD-200108			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Methotrexate			S	Unknown			Accord

Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Zostavax		S	Subcutaneous		Not Reported
	Cortisone		C	Subcutaneous		Not Reported
	Diclofenac		C	Subcutaneous		Not Reported
	Xeljanz		C	Oral	2 Every 1 Days	Not Reported
	Desoximetasone		C	Subcutaneous		Not Reported
	Xeljanz		C	Oral	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256293	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020182256		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Epigastric Discomfort; Gastric Ulcer Perforation; General Physical Health Deterioration; Hypertension	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cortison			C	Unknown	Unk		Glaxosmithkline
	Enbrel			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256343	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-260053			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Acetylsalicylic Acid			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual
	Heparin			S	Unknown	Unk		Not Reported
	Intravenous Immunoglobulin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256349	EXPEDITED (15-DAY)		DE, OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-260976		64 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Fungal	Methylprednisolone			S	Unknown	24 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Sun
	Ciclosporin			S	Unknown	50 Milligram, Bid		Not Reported
	Amlodipine			C	Unknown	5 Milligram, Qd		Not Reported
	Febuxostat			C	Unknown	40 Milligram, Qd		Not Reported
	Sodium Bicarbonate			C	Unknown	0.5 Gram, Tid		Not Reported
	Warfarin			C	Unknown	2.5 Milligram, Qd		Not Reported
	Torasemide			C	Unknown	10 Milligram, Qd		Not Reported
	Potassium Chloride			C	Unknown	0.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256364	EXPEDITED (15-DAY)		OT	CA-ACCORD-200070		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Methotrexate	S	Parenteral		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Etanercept	S	Unknown		Not Reported
	Humira	S	Subcutaneous	1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Oral	1 Every 2 Weeks	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256511	EXPEDITED (15-DAY)		OT	ES-ADVANZ PHARMA-202008008548			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Film-Coated Tablet (Q12 H)		Concordia
	Methylprednisolone			S	Unknown	60 Mg, Qd		Not Reported
	Lopinavir/Ritonavir			S	Unknown	400/100 Mg, Bid (400/100 Mg/12 H)		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Simvastatine			C		Unk		Not Reported

Omeprazol [Omeprazole]	C	Unk	Not Reported
Hidroferol	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256528	EXPEDITED (15-DAY)		OT	CA-ACCORD-200249		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256638	EXPEDITED (15-DAY)		OT	CA-ACCORD-200265		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported

Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256639	EXPEDITED (15-DAY)		OT	ID-LUPIN PHARMACEUTICALS INC.-2020-05833		49 YR	Female	IDN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Oseltamivir			S	Unknown	75 Milligram, 5-10 Days		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd, 5-7 Days		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Levofloxacin			S	Unknown	250 Milligram, Qd		Lupin
	Levofloxacin			S	Unknown	500 Milligram		Lupin
	Vitamin C [Ascorbic Acid]			C	Unknown	High Dose		Not Reported
	Cotrimoxazole			C	Unknown	1920 Milligram		Not Reported
	Moxifloxacin			C	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256676	EXPEDITED (15-DAY)		OT	CA-ACCORD-200118			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S				Not Reported
	Morphine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Dronabinol			C				Not Reported
	Cannabis Sativa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256685	EXPEDITED (15-DAY)		OT	CA-ACCORD-200250		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Methotrexate	S			Not Reported
	Enbrel	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Remicade	S		Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C		Frequency: 1 Every 1 Days	Not Reported
	Leflunomide	C		Frequency: 1 Every 1 Days	Not Reported
	Xeljanz	C	Oral	Frequency: 1 Every 1 Days	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Xeljanz	C	Oral	Frequency: 1 Every 1 Days	Not Reported
	Xeljanz	C	Oral	Frequency: 1 Every 1 Days	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256793	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-199944		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Accord
	Cefazolin			S	Intramuscular			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported
	Tenofovir		C	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256817	EXPEDITED (15-DAY)		OT	CA-ACCORD-200229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256893	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2020343226		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Drug Ineffective For Unapproved Indication; Off Label Use; Respiratory	Methylprednisolone			S		1 Mg/Kg, 1x/Day		Pfizer
	Piperacillin/Tazobactam			S		Unk		Pfizer

Failure	Voriconazole	S	Intravenous (not otherwise specified)	6 Mg/Kg, 2x/Day	Pfizer
	Voriconazole	S	Intravenous (not otherwise specified)	4 Mg/Kg, 2x/Day	Pfizer
	Ceftriaxone	S		2000 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S		200 Mg, 2x/Day	Not Reported
	Spiramycin	S		1.5 Miu, 3x/Day	Not Reported
	Enoxaparin	S		6000 Iu (Axa)	Not Reported
	Enoxaparin	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256938	EXPEDITED (15-DAY)		OT	CA-ACCORD-200225		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			C	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine			C				Not Reported
	Folic Acid			C	Unknown	1 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826598			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257228	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2020AMR177811			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Benlysta			S	Subcutaneous	200 Mg, We		Glaxosmithkline
	Cellcept			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257309	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28116		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular	Infliximab			S	Unknown	Unknown		Not Reported

Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Adalimumab	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous, Single Use Pre-Filled Syringe, Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous, Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Poweder For Solution Intravenous, Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous, Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Actemra	C	Unknown	Unknown	Not Reported
	Azathioprine	C	Unknown	Unknown	Not Reported
	Minocycline	C	Unknown	Unknown	Not Reported
	Penicillamine	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257408	EXPEDITED (15-DAY)		HO, OT	US-PBT-000469		50 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress	Tacrolimus			S	Unknown			Panacea Biotec

Syndrome; Atrial Flutter; Covid-19	Tacrolimus	S	Unknown		Panacea Biotec
	Mycophenolate Mofetil	S	Unknown		Panacea Biotec
	Mycophenolate Mofetil	S	Unknown		Panacea Biotec
	Mycophenolate Mofetil	S		Mycophenolate Dose Was Reduced By 50%	Panacea Biotec
	Mycophenolate Mofetil	S	Unknown	Mycophenolate Dose Was Reduced By 50%	Panacea Biotec
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown	Reduced To 30 Mg	Not Reported
	Prednisone	S	Unknown	Reduced To 30 Mg	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	One 400-Mg Intravenous (Iv) Dose	Not Reported
	Azithromycin	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydrocortisone	S	Intravenous (not otherwise specified)	Stress-Dose Iv Hydrocortisone	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257416	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826640		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257434	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826491		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	40 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Oral			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257479	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1826999		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea;	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

Synovitis; Tachycardia	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257535	EXPEDITED (15-DAY)		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05768		50 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Crystal Nephropathy; Drug Effective For Unapproved Indication; Hyperoxaluria; Off Label Use; Renal Tubular Injury; Renal Tubular Necrosis	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Vitamin C Acid			S	Intravenous (not otherwise specified)	50 Milligram/Kilogram, Qid		Not Reported
	Tocilizumab			S	Subcutaneous	1 Dosage Form, Single		Not Reported
	Tocilizumab			S				Not Reported
	Lopinavir/Ritonavir			S	Unknown	Unk (200/50 Mg/D)		Not Reported
	Cobicistat;Darunavir			S	Unknown	Unk (800/150 Mg/D)		Not Reported
	Meropenem			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257605	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1077849		13 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Off Label Use	Lopinavir/Ritonavir			S	Oral	Unk Unk, Bid		Mylan
	Hydroxychloroquine			S	Oral	200 Milligram, Bid On First Day		Mylan
	Hydroxychloroquine			S	Oral	100 Milligram, Bid Administered For 4 Days		Mylan
	Meropenem			C	Unknown	60 Milligram/Kilogram, Qd		Mylan

Teicoplanin	C	Unknown	10 Milligram/Kilogram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257755	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1077992		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Encephalopathy; Fall; Myopathy Toxic; Off Label Use; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Subarachnoid Haemorrhage; Tibia Fracture; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydrocortisone			S	Unknown	20 Milligram, Qd(In The Morning)		Mylan
	Hydrocortisone			S	Unknown	10 Milligram, Qd(In The Afternoon)		Mylan
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257964	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257965	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826638			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18258157	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1078072		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Condition Aggravated; Haemodynamic Instability; Hyperkalaemia; Off Label Use; Pneumonia Bacterial; Sepsis; Stenotrophomonas Infection	Tacrolimus			S	Unknown	5 Milligram, Bid		Mylan
	Tacrolimus			S	Unknown	2.5 Milligram, Bid, The Reduction Of Tacrolimus To 2.5mg Two Times A Day		Mylan
	Mycophenolic Acid			S	Unknown	250 Milligram, Bid		Mylan
	Prednisone			S	Unknown	5 Milligram, Qd		Mylan
	Sulphamethoxazole/Trimethoprim			S	Unknown			Mylan
	Sulphamethoxazole/Trimethoprim			S				Mylan
	Hydroxychloroquine			S	Unknown			Mylan
	Azithromycin			S	Unknown			Mylan
	Cefepime			S	Unknown			Mylan
	Atracurium			C	Unknown			Mylan
	Methylprednisolone			C	Intravenous (not otherwise specified)	60 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18258378	EXPEDITED (15-DAY)		OT	NVSC2020CH244323		68 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	600 Mg, Once/Single, On Day 6		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18258501	EXPEDITED (15-DAY)		HO	CN-SGP-000091		64 YR	Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Product Use In Unapproved Indication	Methylprednisolone			S	Unknown	24 Mg Once Daily		Sungen Pharma
	Ciclosporin			S	Unknown	50 Mg Twice Daily		Not Reported
	Hydroxychloroquine			S	Unknown	0.2g Twice Daily		Not Reported
	Amlodipine			S	Unknown	5mg Once Daily		Not Reported
	Febuxostat			S	Unknown	40 Mg Once Daily		Not Reported
	Sodium Bicarbonate			S	Unknown	0.5g Three Times A Day		Not Reported
	Warfarin			S	Unknown			Not Reported
	Torasemide			S	Unknown			Not Reported
	Potassium Chloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18258905	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1076761			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Milligram, Bid		Mylan
	Methotrexate			S	Oral	Seven 2.5mg, Tablets, By Mouth, One Time A Week		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2020	18283098	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Ibrutinib			S				Not Reported
	Hydroxychloroquine			S			5 DAY	Not Reported
	Azithromycin			S			3 DAY	Not Reported
	Tocilizumab			S				Not Reported
	Immunoglobulins, Intravenous			S	Intravenous (not otherwise specified)		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2020	18260020	EXPEDITED (15-DAY)		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-05770		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Crystal Nephropathy; Drug Effective For Unapproved Indication; Hyperoxaluria; Off Label Use; Platelet Count Decreased; Renal Impairment; Renal Tubular Injury	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Linezolid			S	Unknown	Unk		Novel Labs
	Linezolid			S				Novel Labs
	Linezolid			S				Novel Labs
	Ceftriaxone			S	Unknown	Unk		Lupin
	Ceftriaxone			S				Lupin
	Ceftriaxone			S				Lupin
	Vitamin C Acid			S	Intravenous (not otherwise specified)	50 Milligram/Kilogram, Qid		Not Reported
	Lopinavir/Ritonavir			S	Unknown	400 Milligram, Bid		Not Reported
	Cobicistat;Darunavir			S	Unknown	150/800 Milligram, Qd		Not Reported
	Daptomycin			S	Unknown	Unk		Not Reported
	Daptomycin			S				Not Reported
	Daptomycin			S				Not Reported
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			S				Not Reported

	Piperacillin/Tazobactam	S			Not Reported
	Meropenem	S	Unknown	Unk	Not Reported
	Meropenem	S			Not Reported
	Meropenem	S			Not Reported
	Oxacillin	S	Unknown	Unk	Not Reported
	Oxacillin	S			Not Reported
	Oxacillin	S			Not Reported
	Metformin	C	Unknown		Not Reported
	Insulin	C	Unknown	Unk (Long-Acting)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2020	18260021	EXPEDITED (15-DAY)		OT	TW-LUPIN PHARMACEUTICALS INC.-2020-05772		44 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Lupin
	Heparin			C	Unknown	20 International Unit/Kilogram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2020	18260212	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026346			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous	162.0 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Milligram 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Oral	10.0 Milligram, 1 Every 1 Days	Not Reported
	Orencia	S	Subcutaneous	125.0 Milligram, 1 Every 1 Weeks	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	14535482	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthralgia; Arthropathy; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Foot Deformity; Foot Operation; Hepatotoxicity; Ill-Defined Disorder; Infection; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Neck Pain; Nodule; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous		Not Reported
Gold	S	Unknown		Not Reported
Plaquenil	S			Not Reported
Plaquenil	S	Oral		Not Reported
Apo-Hydroxyquine	S			Not Reported
Methotrexate	S	Subcutaneous	Dose: 17.5 Mg	Not Reported
Methotrexate	S			Not Reported
Actonel	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Codeine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	300 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Intravenous (not otherwise specified)		Not Reported

	Prednisone	C	Unknown		Not Reported
	Adalimumab	C	Unknown		Not Reported
	Adalimumab	C			Not Reported
	Xeljanz	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	14535544	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0125		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous	100 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	500 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral	12.5 Mg		Not Reported

Methotrexate	S	Oral			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg		Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg		Not Reported
Methotrexate	S	Oral	12.5 Mg		Not Reported
Methotrexate	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Leflunomide	S	Oral			Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C				Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	14535557	EXPEDITED (15-DAY)		CA, OT	CA-BIOVITRUM-2018CA0126			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Methotrexate Sodium	S	Subcutaneous	Not Reported
Naprosyn	S	Oral	Not Reported
Naprosyn	S	Oral	Not Reported
Naprosyn	S	Oral	Not Reported
Naprosyn	S	Unknown	Not Reported
Orencia	S	Endocervical	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Vioxx	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Naproxen	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	14535636	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Apo Hydroxyquine	S		Not Reported
	Apo-Mycophenolate	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S		Not Reported
	Celebrex	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C		Not Reported
	Celebrex	C	Unknown	Not Reported

	Prednisone	C	Intravenous (not otherwise specified)		Not Reported
	Humira	C	Subcutaneous		Not Reported
	Humira	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	15065924	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0717		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown	300 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous drip		Not Reported
Rituxan	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Humira	S	Unknown	40 Mg	Not Reported
Humira	S	Unknown	40 Mg	Not Reported
Humira	S			Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown	200.0 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	200.0 Milligram	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S			Not Reported
Methotrexate	S		15 Mg	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Actemra	S	Unknown	1825 Days	Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Leflunomide	S	Oral	730 Days	Not Reported
Apo-Leflunomide	S	Oral	20 Mg	Not Reported
Arava	S	Unknown		Not Reported

Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	200.0 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Bupropion	C	Oral		Not Reported
Sulfasalazine	C			Not Reported
Wellbutrin	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	15100606	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0751		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported

Abnormal; Shoulder Arthroplasty; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	15573002	EXPEDITED (15-DAY)		DS, OT	US-SA-2018SA298977			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Increased Tendency To Bruise; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling;	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported

Platelet Count Decreased;
Rheumatoid Arthritis;
Therapy Interrupted

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	15620857	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556897-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	15790320	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018149717		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Immunosuppression; Infection; Influenza; Pyrexia; Rhinorrhoea; Tachycardia; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Twice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	15897378	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-002605		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness;	Topicort			S	Topical			Not Reported
	Topicort			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Subcutaneous			Not Reported
	Desoximetasone			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Valeant
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound			otherwise specified)		
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	1 Every 1 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported

Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Reactine[Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
Remicade	S	Subcutaneous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration 365 (Unspecified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 365 (Unspecified)	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Apo Folic	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Stelara	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	15955012	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011527			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine /00884302/	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	16155553	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728553-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Orencia	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Leflunomide	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Folic Acid	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	16424233	EXPEDITED (15-DAY)		OT	JP-GLAXOSMITHKLINE-JP2019JPN103475		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyslipidaemia; Enterocolitis; Herpes Zoster; Inappropriate Schedule Of Product Administration; Influenza; Insomnia; Neuralgia	Belimumab			S	Intravenous drip	10 Mg/Kg, 1d		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every 2 Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every 4 Weeks		Glaxosmithkline
	Belimumab			S	Subcutaneous	200 Mg, We		Glaxosmithkline
	Belimumab			S	Subcutaneous	200 Mg, We		Glaxosmithkline
	Prednine			S	Oral	5 Mg, 1d		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Oral	Unk		Not Reported
	Nexium Capsule			C		Unk		Not Reported
	Ferrous Sodium Citrate			C		Unk		Not Reported
	Polaprezinc Od			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	16739475	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-23772		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Pregabalin	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17015578	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457943		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	4.0 Month		Not Reported
	Arava			S	Oral	91 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	4.0 Year		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	731.0		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous	6.0 Month		Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Hydromorphone Hcl			C	Unknown			Not Reported
	Leflunomide			C	Unknown	4.0 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17227953	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162567		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate	S	Unknown		Barr
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17236303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509500		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C	Oral			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17244861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510478		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Product Use In Unapproved Indication; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 411.0		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17260314	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518102		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood	Actemra			S	Unknown			Not Reported

Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Anakinra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17364200	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533943		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Actemra	S	otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Therapy Duration: 84 Days	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Chlorhexidine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single Use	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Oxycodone Terephthalate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Periarticular		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Periogard	S	Unknown		Not Reported
	Periogard	S	Unknown		Not Reported
	Act Oxycodone Cr	S	Unknown		Not Reported

Sulfamethoxazole	S	Unknown		Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Chlorhexidine Gluconate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Acetaminophen;Oxycodone Hydrochloride	S	Unknown		Not Reported
Apo-Acetaminophen	S	Unknown		Not Reported
Chloraprep	S	Topical	O	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Oxycodone And Acetaminophen	S	Unknown		Not Reported
Abatacept	S	Intravenous (not otherwise specified)		Not Reported
Arava	C	Oral		Not Reported
Desogestrel;Ethinylestradiol	C			Not Reported
Ibuprofen	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole Sodium	C			Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Oral		Not Reported
Reactine (Canada)	C			Not Reported
Tylenol	C			Not Reported
Hydroxychloroquine Sulfate	C			Not Reported
Cetirizine Hydrochloride	C			Not Reported
Pantoprazole	C			Not Reported
Paracetamol	C			Not Reported
Cetrizine	C	Unknown		Not Reported
Hydroxychloroquine Phosphate	C	Unknown		Not Reported
Paracetamol Codeine	C	Unknown		Not Reported
Tylenol With Codeine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17433130	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0820		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure; Vasculitic Rash	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg (2 Year Duration)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg (Duration 2 Years)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg (1 Year)	Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Cyclical	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Once Every Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown	20 Mg	Not Reported

Leflunomide	S	Oral	20 Mg		Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Remicade	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral			Not Reported
Methotrexate	S	Oral			Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg		Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram		Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Oral	12.5 Mg		Not Reported
Methotrexate	S	Oral	12.5 Mg		Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C	Oral	5 Mg		Not Reported
Xeljanz	C				Not Reported
Amlodipine	C				Not Reported
Cimzia	C	Subcutaneous			Not Reported
Dilaudid	C				Not Reported
Eletriptan	C				Not Reported
Hydromorph Contin	C				Not Reported
Methotrexate	C				Not Reported
Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17450107	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BIOVITRUM-2020CA0815		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Kineret			S	Subcutaneous			Not Reported

Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Poor Venous Access; Prescribed Underdose; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Pyrexia; Quality	Kineret	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous	12.5 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S		280 Mg	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S			Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S			Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	1.5 Mg	Not Reported
	Enbrel	S	Subcutaneous	12.5	Not Reported
	Humira	S	Subcutaneous	1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported

Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Naproxen Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral	1.3 Mg	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone	S	Intra-articular		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo Prednisone	S	Oral		Not Reported
	Apo Prednisone	S	Oral		Not Reported
	Apo Prednisone	S	Oral		Not Reported
	Apo Prednisone	S	Oral		Not Reported
	Apo Prednisone	S	Oral	1.3 Mg	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral		Not Reported

	Apo-Prednisone	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	1 Every 1 Day	Not Reported
	Triamcinolone Acetonide	C	Intra-articular		Not Reported
	Triamcinolone Acetonide	C	Unknown		Not Reported
	Triamcinolone Acetonide	C	Oral		Not Reported
	Triamcinolone Acetonide	C	Intra-articular		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17661791	EXPEDITED (15-DAY)		OT	NVSC2020CA096874		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Methotrexate			S	Subcutaneous	20 Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg/Kg		Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Plaquenil		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Oral	Unk	Not Reported
	Xeljanz		C	Oral	5.0 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17724510	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1948		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Kineret			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Naproxen	S	Unknown	1000 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Plaquenil	S			Not Reported
Erelzi	S	Unknown		Not Reported
Acetaminophen	C	Oral		Not Reported
Diphenhydramine Hydrochloride	C	Oral		Not Reported
Ferrous Gluconate	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Lasix	C	Unknown		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
Naprosyn	C	Unknown		Not Reported
Oxycontin	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17749452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592483		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Contraindicated	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Product Administered; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Anakinra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17815756	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0739		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Desoximetasone	C	Oral	Not Reported
Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17848664	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606545		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue;	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 84.0 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Pain; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased			otherwise specified)	
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Act Oxycodone Cr	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Not Reported
	Simponi	S	Periarticular	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Periogard	S	Unknown	Not Reported
	Chloraprep	S	Unknown	Not Reported

	Tylenol	C	Unknown	Not Reported
	Reactine (Canada)	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Pantoloc	C		Not Reported
	Arava	C		Not Reported
	Cetrizine	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Ibuprofen	C		Not Reported
	Desogestrel;Ethinylestradiol	C		Not Reported
	Paracetamol/Codeine	C		Not Reported
	Plaquenil	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17862918	EXPEDITED (15-DAY)		DS	CA-ROCHE-2609114		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability;	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1.0 Months		Not Reported
	Adalimumab			S	Subcutaneous	4.0 Years		Not Reported
	Etanercept			S	Unknown	404.0 Days		Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	1898.0 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Erelzi			S	Unknown	404.0 Days		Not Reported

Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17971391	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2020-031307		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Pressure Increased; Clonus; Delirium; Depressed Level Of Consciousness; Drug Interaction; Encephalopathy; Hyperhidrosis; Hyperreflexia; Myoclonus; Off Label Use; Serotonin Syndrome; Speech Sound Disorder; Tachycardia; Urinary Retention	Duloxetine			S	Oral	120 Milligram, Once A Day		Aurobindo
	Duloxetine			S				Aurobindo
	Haloperidol			S	Oral	1 Milligram, Two Times A Day		Not Reported
	Haloperidol			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Once A Day		Not Reported
	Lithium			S	Oral	800 Milligram, Once A Day		Not Reported
	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Two Times A Day (400 Mg/ 100 Mg)		Not Reported
	Haloperidol			C	Unknown	2 Milligram, Once A Day (Twice Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18010319	EXPEDITED (15-DAY)		HO, OT	NVSC2020LT182621		55 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aphasia; Asthenia; Ataxia; Balance Disorder; Blepharospasm;	Methotrexate			S	Unknown	15 Mg, Qw, Dose Was Increased To 15 Mg Per Week		Novartis

Bradyphrenia; Brain Oedema; Chills; Coordination Abnormal; Disorientation; Dizziness; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Dysarthria; Encephalitis Viral; Headache; Leukopenia; Movement Disorder; Nausea; Neurological Symptom; Normochromic Normocytic Anaemia; Osteoporosis; Pancytopenia; Pyrexia; Rebound Effect; Rheumatoid Arthritis; Somnolence; Thrombocytopenia; Tick-Borne Viral Encephalitis; Transaminases Increased; Vomiting	Methylprednisolone	S	Unknown	12 Mg, Qd	Not Reported
	Methylprednisolone	S	Unknown	Reduced Dose	Not Reported
	Methylprednisolone	S	Unknown	Glucocorticoids Treatment Was Renewed	Not Reported
	Infliximab	S	Unknown	3 Mg/Kg, Two Courses	Not Reported
	Infliximab	S	Unknown	3 Mg/Kg (Two Courses, Last Dose Was Injected One Week Earlier (On The 24th Of July 2019))	Not Reported
	Folic Acid	S	Unknown	Verapamil/Trandolapril 240 Mg/4 Mg, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Lornoxicam	S	Unknown	8 Mg, Bid	Not Reported
	Lornoxicam	S	Unknown	8 Mg, Q12h	Not Reported
	Ceftazidime	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Trandolapril	S	Unknown	Unk (240mg/4mg)	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Mannitol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18078888	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP014469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Azathioprine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18090718	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP013458			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	2 Milligram, Qd		Not Reported
	Celecoxib			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18158397	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP015697		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Asthma; Blood Count Abnormal; Cardiac Dysfunction; Chest Discomfort; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Conjunctival Hyperaemia; Eye Pruritus; Flushing; Ill-Defined Disorder; Obstructive Airways Disorder; Rash; Rash Pruritic; Respiratory Tract Congestion; Rhinitis; Rhinorrhoea; Sinus Headache; Sinusitis; Therapeutic Product Effect Incomplete; Upper-Airway Cough Syndrome; Urinary Tract Infection; Vasculitis	Salbutamol	S		2 Dosage Form	Apotex
	Ciclesonide	S	Unknown	1 Dosage Form, Qd	Apotex
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Zenhale	S		2 Dosage Form, Bid	Not Reported
	Azathioprine	C	Oral	125 Milligram, Qd	Not Reported
	Levothyroxine Sodium	C	Oral	150 Microgram	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
	Risedronate	C	Oral	150 Milligram	Not Reported
	Saline [Sodium Chloride]	C	Unknown	Unk	Not Reported
	Synthroid	C	Oral	150 Microgram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18161669	EXPEDITED (15-DAY)		OT	CA-ROCHE-2657390			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18168234	EXPEDITED (15-DAY)		OT	NL-LUPIN PHARMACEUTICALS INC.-2020-04793		39 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Exposure During Pregnancy; Off Label Use	Betamethasone			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18236123	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-LUPIN PHARMACEUTICALS INC.-2020-05496		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Cardiac Arrest; Cardiogenic Shock; Cardiomyopathy; Cardiopulmonary Failure; Electrocardiogram Qt Prolonged; Left Ventricular Failure; Pleural Effusion; Pulmonary Congestion; Respiratory Failure	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (1-0-1 For 4 Years, Previously For 5 Years 1-0- 0, Cumulative Dose About 950 G)		Lupin
	Naloxone;Tilidine			C	Unknown	150/12 Mg , Bid		Not Reported
	Torasemide			C	Unknown	20 Milligram, Qd		Not Reported
	L-Thyroxine [Levothyroxine]			C	Unknown	75 Microgram, Qd		Not Reported
	Allopurinol			C	Unknown	100 Milligram, Qd		Not Reported
	Ibandronic Acid			C	Unknown	50 Milligram,3 Times A Week		Not Reported
	Metamizole			C	Unknown	500 Milligram, Tid		Not Reported
	Vitamin D Nos			C	Unknown	Unk		Not Reported
	Ciprofloxacin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18243357	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1076803		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Off Label Use; Tachyarrhythmia; Tachycardia; Vomiting; Weight Decreased	Azithromycin			S	Oral	500 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	200 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18246105	EXPEDITED (15-DAY)		HO, LT, OT	US-STRIDES ARCOLAB LIMITED-2020SP010634		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Embolic Stroke; Encephalomalacia; Encephalopathy; Fall; Hypercapnia; Muscle Injury; Myopathy; Pneumonia; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Subarachnoid Haemorrhage; Tibia Fracture	Hydrocortisone			S	Unknown	20 Milligram, Every Morning		Strides
	Hydrocortisone			S	Unknown	10 Milligram,Qd (In The Afternoon)		Strides
	Hydroxychloroquine			S	Unknown	Prolonged Hiatus (From Age 40 To 42)		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Every 12 Hrs (From Age 40 To 42)		Not Reported
	Hydroxychloroquine			S	Unknown	Restarted		Not Reported
	Anakinra			C	Subcutaneous	100 Milligram Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260369	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05903		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cervical Vertebral Fracture; Diaphragm Muscle Weakness; Encephalopathy; Fall; Myopathy Toxic; Pneumothorax; Respiratory Acidosis; Respiratory Failure; Subarachnoid Haemorrhage; Tibia Fracture; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	Unk (From Mid 20'S To 40years Of Age)		Lupin
	Hydrocortisone			S	Unknown	30 Milligram, Qd (20mg Every Morning And 10mg In The Afternoon)		Lupin
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260437	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826459		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260466	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826494		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260476	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic	Methotrexate			S	Unknown			Barr

Enzyme Increased; Pneumonia	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260485	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1826639		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260492	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1825643		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Hidroxicloroquina (2143a)			S		Unit Dose 200mg		Teva
	Azitromicina (7019a)			S		Unit Dose 500mg		Not Reported
	Lopinavir+Ritonavir			S		4 Dosage Forms Daily; 2 Cp / 12 Hours		Not Reported

	Polaramine	C	Unit Dose 6mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260537	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1825964		93 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva
	Kaletra 200 Mg/50 Mg Film-Coated Tablets			C	Oral	250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260836	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2020-05853		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rebound Effect	Methylprednisolone			S	Oral	1 Milligram/Kilogram, Unk		Lupin
	Methylprednisolone			S	Unknown	Unk (Dose Reduction)		Lupin
	Methylprednisolone			S	Unknown	Unk (Resumed In The Form Of Systemic Therapy)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Hydroxychloroquine			S				Lupin
	Dimethyl Fumarate			C	Unknown	120 Milligram, Qd		Not Reported
	Dimethyl Fumarate			C				Not Reported
	Prednisolone			C	Unknown	5 Milligram, Qd (Low Dose)		Not Reported
	Prednisolone			C				Not Reported
	Ciprofloxacin			C	Oral	500 Milligram, Tid		Not Reported
	Ciprofloxacin			C				Not Reported
	Clindamycin			C	Oral	300 Milligram, Bid		Not Reported
	Clindamycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260838	EXPEDITED (15-DAY)		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2020-05865		13 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Oral	200 Milligram, Bid (On First Day)		Lupin
	Hydroxychloroquine			S	Oral	100 Milligram, Bid (Administered For 4 Days)		Lupin
	Vincristine			C	Unknown	Unk		Not Reported
	Teicoplanin			C	Unknown	10 Milligram/Kilogram, Qd		Not Reported
	Doxorubicin			C	Unknown	Unk		Not Reported
	Meropenem			C	Unknown	60 Milligram/Kilogram, Qd		Not Reported
	Cyclophosphamide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260858	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-05866		2 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	6.5 Milligram/Kilogram, Qd		Lupin
	Vincristine			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	50 Milligram/Kilogram, Bid		Not Reported
	Actinomycin D			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260867	EXPEDITED (15-DAY)		OT	CA-ACCORD-200226			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated;	Methotrexate			S	Oral			Not Reported
	Anakinra			S				Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Arava	S	Oral	1 Every 1 Days		Not Reported
	Enbrel	S		2 Every 1 Weeks		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S				Not Reported
	Hydroxychloroquine	S				Not Reported
	Naproxen	S		2 Every 1 Days		Not Reported
	Orencia	S				Not Reported
	Rituximab	S				Not Reported
	Vioxx	S				Not Reported
	Xeljanz	C		2 Every 1 Days		Not Reported
	Leflunomide	C				Not Reported
	Methotrexate	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18260973	EXPEDITED (15-DAY)		OT	CH-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-246275		68 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haemolytic Anaemia	Hydroxychloroquine			S	Unknown	Unk,		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261024	NON-EXPEDITED			US-ADVANZ PHARMA-202009008541			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261314	EXPEDITED (15-DAY)		OT	NVSC2020CA247351			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug	Neoral			S	Unknown	125 Mg, Bid		Novartis
	Methotrexate			S	Oral	Unk		Not Reported

Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	1 Df, Qw	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Azathioprine	S	Unknown	150 Mg, Tid	Not Reported
	Azathioprine Sodium	S	Unknown	150 Mg, Unknown	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Citalopram Hydrobromide	C	Unknown	1 Df, Qw	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg, Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261458	EXPEDITED (15-DAY)		DE, HO, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260759		35 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Pneumonia	Azithromycin			S	Oral	500 Milligram		Sun
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Methylprednisolone			S	Intramuscular	40 Milligram		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	0.6 Unk		Not Reported
	Favipiravir			S	Oral	200 Milligram		Not Reported

Enfluvir	S	Oral	75 Milligram		Not Reported
Plaquenil	S	Oral	200 Milligram		Not Reported
Piperacillin	S	Intravenous (not otherwise specified)	4.5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261459	EXPEDITED (15-DAY)		HO, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-260776		217 DAY	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	500 Milligram		Sun
	Ceftriaxone			S	Transplacental	1 Gram		Not Reported
	Methylprednisolone			S	Transplacental	40 Gram		Not Reported
	Favipiravir			S	Transplacental	200 Milligram		Not Reported
	Enfluvir			S	Transplacental	75 Milligram		Not Reported
	Plaquenil			S	Transplacental	200 Milligram		Not Reported
	Enoxaparin			S	Transplacental	0.6 Unk		Not Reported
	Piperacillin			S	Transplacental	4.5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261632	EXPEDITED (15-DAY)		OT	CA-ACCORD-200467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261636	EXPEDITED (15-DAY)		OT	CA-ACCORD-200495			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Infection; Leukopenia; Lymphopenia; Rash; Serum Ferritin Increased; Systemic Lupus Erythematosus; Transient Ischaemic Attack; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Atorvastatin			C				Not Reported
	Bisoprolol			C				Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Mycophenolic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261638	EXPEDITED (15-DAY)		DE, HO	CN-TEVA-2020-CN-1827257		64 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Penicillium Infection; Pleural Effusion; Pneumonia Fungal	Ciclosporin			S	Unknown	100 Milligram Daily;		Ivax
	Methylprednisolone			S	Unknown	24 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	.4 Gram Daily;		Not Reported
	Amlodipine			C	Unknown	5 Milligram Daily;		Not Reported
	Febuxostat			C	Unknown	40 Milligram Daily;		Not Reported
	Sodium-Bicarbonate			C	Unknown	Administered Three Times A Day		Not Reported
	Warfarin			C	Unknown	2.5 Milligram Daily;		Not Reported

Torasemide	C	Unknown	10 Milligram Daily;		Not Reported
Potassium-Chloride	C	Unknown	.5 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261648	EXPEDITED (15-DAY)		DS	CA-ACCORD-200465		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261720	EXPEDITED (15-DAY)		OT	CA-ACCORD-200498			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Humira	C	Solution Subcutaneous		Not Reported
	Pantoloc	C			Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261721	EXPEDITED (15-DAY)		OT	CA-ACCORD-200456		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Pulmonary Fibrosis; Treatment Failure	Methotrexate			S	Unknown			Accord
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Desoximetasone			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261726	EXPEDITED (15-DAY)		OT	CA-ACCORD-200358		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Hypoaesthesia; Joint Swelling; Muscular Weakness; Nerve Injury;	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Sulfasalazine			S	Unknown	2 Every 1 Days		Not Reported
	Actonel Xr			C	Unknown			Not Reported

Pain; Product Use Issue; Sciatica; Spinal Stenosis	Baclofen	C	Unknown	Every 1 Days	Not Reported
	Folic Acid	C	Unknown	1 Every 1 Days	Not Reported
	Lyrica	C	Unknown	1 Every 1 Days	Not Reported
	Prednisone	C	Oral	1 Every 1 Days, Not Specified	Not Reported
	Ergocalciferol	C	Unknown	Every 1 Days Not Specified	Not Reported
	Hydroxychloroquine	S	Unknown	1 Every 1 Days	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261730	EXPEDITED (15-DAY)		OT	CA-ACCORD-200429		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Accord
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tylenol			C				Not Reported
	Simponi			C				Not Reported
	Remicade			C				Not Reported
	Rabeprazole/Rabeprazole Sodium			C				Not Reported
	Orencia			C				Not Reported
	Lyrica			C				Not Reported
	Humira			C				Not Reported
	Cimzia			C				Not Reported
	Arthrotec			C				Not Reported
	Actemra			C				Not Reported
	Codeine/Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261759	EXPEDITED (15-DAY)		OT	CA-ACCORD-200343			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Methotrexate			S	Unknown	Not Specified		Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261771	EXPEDITED (15-DAY)		OT	CA-ACCORD-200175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Skin Cancer; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral	Not Specified		Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18261953	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020346748		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Meropenem			S		Unk		Pfizer
	Norepinephrine Bitartrate			S		Unk		Pfizer
	Atracurium Besilate			S		Unk		Pfizer
	Propofol			S		Unk		Pfizer
	Fentanyl Citrate			S		Unk		Pfizer

	Hydroxychloroquine	S	Unk	Not Reported
	Phenylephrine	S	Unk	Not Reported
	Vasopressin	S	Unk	Not Reported
	Tocilizumab	S	Unk	Not Reported
	Heparin Sodium	C	Unk	Not Reported
	Acetylsalicylic Acid	C	81 Mg	Not Reported
	Clopidogrel	C	75 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262073	EXPEDITED (15-DAY)		OT	NVSC2020CA163624		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw (1 Every Week)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg/Kg		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Orencia	S	Subcutaneous	12.5 Mg, Unknown		Not Reported
Sulfasalazine	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Apo-Leflunomide	S	Oral	Unk		Not Reported
Xeljanz Xr	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2673837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Intravenous drip	Solution For Injection		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported

Methotrexate Sodium	S	Unknown			Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Oral			Not Reported
Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262445	EXPEDITED (15-DAY)		OT	NVSC2020CA096804		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown			Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Rituximab			S	Unknown	8.0 Mg/Kg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Tablet	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Tablet	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg (Solution For Infusion)	Not Reported
Enbrel	S	Unknown	50 Mg, Qd	Not Reported
Orencia	S	Unknown	125 Mg, Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown	Not Reported
Sulfasalazine	S	Oral		Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Unknown	2 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262488	EXPEDITED (15-DAY)		OT	NVSC2020CA247377		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk (Intravenous Drip)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Subcutaneous	200.0 Mg, Unknown		Not Reported
	Methotrexate			S	Subcutaneous	200.0 Mg, Unknown		Not Reported
	Methotrexate			S	Oral	20.0 Mg, Unknown		Not Reported
	Methotrexate			S	Oral	20.0 Mg, Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unknown (Dosage Form Not Specified)		Not Reported

Apo-Leflunomide	S	Oral	Unk	Not Reported
Enbrel	S	Unknown	50.0 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	50.0 Mg, Qw	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125.0 Mg, Unknown	Not Reported
Orencia	S	Subcutaneous	125.0 Mg, Unknown	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3.0 Mg, Unknown	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262493	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28178		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported

Orencia	S	Unknown	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unknown		Not Reported
Pregabalin	S	Unknown	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Simponi	S	Unknown	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262810	EXPEDITED (15-DAY)		HO, OT	IT-TEVA-2020-IT-1827271		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Crystal Nephropathy; Off Label Use; Platelet Count Decreased; Renal Impairment; Renal Tubular Injury	Hydroxychloroquine			S	Unknown	800 Milligram Daily;		Teva
	Vitamin C			S	Intravenous (not otherwise specified)	200 Mg/Kg Daily;		Not Reported
	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported
	Cobicistat/Darunavir			S	Unknown	150/800 Mg/Day		Not Reported
	Lopinavir/Ritonavir			S	Unknown	200/50mg		Not Reported
	Linezolid			S	Unknown			Not Reported
	Linezolid			S				Not Reported
	Linezolid			S				Not Reported
	Metformin			C	Unknown			Not Reported
	Piperacillin/Tazobactam			C	Unknown			Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Meropenem			C	Unknown			Not Reported
	Meropenem			C				Not Reported

Meropenem	C					Not Reported
Daptomycin	C	Unknown				Not Reported
Daptomycin	C					Not Reported
Daptomycin	C					Not Reported
Oxacillin	C	Unknown				Not Reported
Oxacillin	C					Not Reported
Oxacillin	C					Not Reported
Insulin	C	Unknown	Long-Acting			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262811	EXPEDITED (15-DAY)		HO, OT	IT-TEVA-2020-IT-1827270		50 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Crystal Nephropathy; Off Label Use; Renal Tubular Injury; Renal Tubular Necrosis	Hydroxychloroquine			S	Unknown	800 Milligram Daily;		Teva
	Vitamin C			S	Intravenous (not otherwise specified)	200 Mg/Kg Daily;		Not Reported
	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported
	Cobicistat/Darunavir			S	Unknown	150/800 Mg/Day		Not Reported
	Lopinavir/Ritonavir			S	Unknown	200/50 Mg/Day		Not Reported
	Tocilizumab			S	Subcutaneous	Single Dose		Not Reported
	Tocilizumab			S				Not Reported
	Meropenem			C	Unknown			Not Reported
	Meropenem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263707	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28246			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

	Plaquenil	S	Unknown	Unknown		Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Rituximab	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Levothyroxine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263911	EXPEDITED (15-DAY)		OT	NVSC2020US250587			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18264260	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-025899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Liver Injury; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride Plus Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Etanercept	S	Subcutaneous	Not Reported
Etanercept	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Calcium Gluconate	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Quetiapine	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18264602	EXPEDITED (15-DAY)		OT	CA-SA-2020SA248744			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endocarditis; Hepatic Enzyme Increased; Urinary Retention	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18264801	EXPEDITED (15-DAY)		CA, OT	IT-AMNEAL PHARMACEUTICALS-2020-AMRX-02789			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Brain Damage; Congenital Cytomegalovirus Infection; Congenital Hearing Disorder; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Azathioprine			S	Transplacental	Unk		Amneal
	Hydroxychloroquine Sulfate			S	Transplacental	Unk		Amneal
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18265060	EXPEDITED (15-DAY)		HO	TR-AMNEAL PHARMACEUTICALS-		47 YR	Male	TUR

2020-AMRX-02810

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenic Syndrome; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Single		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18265755	EXPEDITED (15-DAY)		OT	CA-ROCHE-2675097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18304663	DIRECT					50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Meningitis Viral; Photophobia; Seizure	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	10991568	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150323608		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Infection; Lip Swelling; Synovitis	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	11837544	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015337333		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthritis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Off Label Use; Pneumonia; Treatment Failure	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S		Unk, Qmo (8.0 Mg/Kg)		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Remicade	S		Unk		Not Reported
Cortisone	C	Oral	5 Mg		Not Reported
Prednisone	C		Unk		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported
Desoximetasone	C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	13901720	EXPEDITED (15-DAY)		OT	PHHY2017CA124492		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Treatment Failure	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Novartis
	Neoral			S	Subcutaneous	Unk (15 Years)		Not Reported
	Neoral			S	Oral	Unk (15 Years)		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk (2 Months)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk (3 Months)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, (01 Every 01 Weeks)		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk (15 Years)		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg (16 Years)		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk (Powder For Solution Intravenous)		Not Reported
	Xeljanz			C	Oral	2 Df, Qd (5 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	13903125	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP016854		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Rheumatoid Arthritis; Sciatica; Treatment Failure	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Apotex
	Apo-Ramipril			S	Unknown	1 Df, Qd		Apotex
	Apo-Ramipril			S	Unknown	Unk Unk, Qd		Apotex
	Apo-Ramipril			S	Unknown	1 Mg, Qd		Apotex
	Apo-Ramipril			S	Oral	Unk Qd		Apotex
	Apo-Prednisone			S	Unknown	7 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	7 Mg, Unk		Apotex
	Apo-Prednisone			S	Oral	7 Milligram, Qd		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	Unk		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	2 Df, Qd		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	Unk, Qd		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk, Q.12h		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Mg, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk Unk, Qd		Not Reported
	Levothyroxine			S	Unknown	Unk Every One Day		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	1 Df, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported

Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Cosopt	S	Unknown	Unk, Bid	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk Unk, Prn	Not Reported
Acetaminophen, Caffeine And Dihydrocodeine Bitartrate	C	Unknown		Not Reported
Dorzolamide Hydrochloride W/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported
Plaquenil /00072602/	C	Unknown	400 Mg, Qd	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Caffeine	C	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported

	Tylenol With Codein /00116401/	C	Unknown	Unk	Not Reported
	Caffeine Citrate W/Codeine Phosphate/Paraceta	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	400 Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	14251906	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021818			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Apo-Acetaminophen			S	Unknown	325 Milligram		Apotex
	Apo-Acetaminophen			S				Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Apotex
	Apo-Prednisone			S	Oral	20 Nanogram		Apotex
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.I.W		Not Reported
	Enbrel			S	Unknown	50 Milligram, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Synthroid	C				Not Reported
Methotrexate	C	Unknown	25 Df, Q.Wk.		Not Reported
Methotrexate	C	Unknown	25 Milligram, Q.Wk.		Not Reported
Methotrexate	C	Unknown	20 Milligram, Q.Wk.		Not Reported
Methotrexate	C	Unknown	Unk, Once In Every Four Weeks		Not Reported
Leflunomide	C	Oral	Unk		Not Reported
Phosphoric Acid	C	Unknown	Unk		Not Reported
Codeine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	14739451	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009202			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine		S	Unknown	Unk	Not Reported
	Tylenol /00020001/		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	15042955	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021658		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	15843598	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190118854		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Simponi	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arthrotec	C	Oral	Not Reported
	Gold	C	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	16079812	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2017-00419		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red	Etanercept	S	otherwise specified)		Not Reported
	Etanercept	S	Subcutaneous	Unknown	Not Reported
	Etanercept	S	Unknown	Unknown	Not Reported
	Adalimumab	S			Not Reported
	Abatacept	S	Subcutaneous	Unknown	Not Reported
	Apremilast	S	Unknown	Unknown	Not Reported
	Apremilast	S	Unknown	Unknown	Not Reported
	Apremilast	S	Oral		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Golimumab	S	Unknown		Not Reported
	Golimumab	S	Subcutaneous	Unknown	Not Reported
	Ibuprofen	S	Unknown	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Sulfasalazine	S	Endocervical	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported

Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Ustekinumab	S	Subcutaneous	Unknown	Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Ustekinumab	S	Unknown	Unknown	Not Reported
	Apo-Cyclosporine	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Cimzia	S	Unknown	Solution Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Unknown	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Unknown		Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Unknown		Not Reported
	Motrin	S	Oral	Unknown	Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Otezla	S	Oral		Not Reported
	Otezla	S	Oral	Unknown	Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Otezla	S	Oral		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Simponi	S	Unknown	Solution Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Stelara	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported

Stelara	S	Unknown		Not Reported
Stelara	S	Unknown	Unknown Solution Subcutaneous	Not Reported
Stelara	S	Unknown	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown	Not Reported
Apo Ibuprofen	S	Oral		Not Reported
Sulfamethoxazole	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Celebrex	S	Oral		Not Reported
Codeine	S	Unknown	Unknown	Not Reported
Cosentyx	S	Unknown	Unknown	Not Reported
Cyclosporin	S	Oral	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Intravenous (not		Not Reported

		otherwise specified)		
Rituximab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Colchicine	C	Unknown		Not Reported
Colchicine	C	Unknown	Unknown	Not Reported
Colchicine	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Febuxostat	C	Unknown	Unknown	Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Mogadon	C	Oral		Not Reported
Mogadon	C	Unknown		Not Reported
Mogadon	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown	Unknown	Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown	(Extended- Release)	Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown	Unknown Extended Release	Not Reported
Oxyneo	C	Unknown	Extended Release	Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Oral		Not Reported
Oxyneo	C	Oral		Not Reported
Uloric	C	Unknown		Not Reported

Uloric	C	Oral		Not Reported
Uloric	C	Unknown		Not Reported
Uloric	C	Unknown	Unknown	Not Reported
Uloric	C	Unknown		Not Reported
Uloric	C	Unknown	Unknown	Not Reported
Uloric	C	Unknown		Not Reported
Uloric	C	Unknown		Not Reported
Uloric	C	Unknown	Unknown	Not Reported
Uloric	C	Unknown		Not Reported
Uloric	C	Oral		Not Reported
Nitrazepam	C	Oral	Unknown	Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown	Unknown	Not Reported
Nitrazepam	C	Unknown	Unknown	Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Oral	Unknown	Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Delayed Release	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown	Unknown	Not Reported
Methotrexate Sodium	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	Unknown	Not Reported
Risedronate Sodium	C	Oral		Not Reported
Risedronate Sodium	C	Oral	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Naproxen	C	Unknown		Not Reported

Cannabis Sativa	C	Unknown	Unknown		Not Reported
Actonel	C	Oral			Not Reported
Actonel	C	Oral	Unknown		Not Reported
Acide Folique	C	Unknown	Unknown		Not Reported
Vitamin D 3	C	Oral			Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Adalimumab	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	16125329	EXPEDITED (15-DAY)		OT	PHHY2019CA064258		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Subcutaneous			Novartis
	Methotrexate Disodium			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate Disodium			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Disodium			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Disodium			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Disodium			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate Disodium			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Disodium			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate Disodium			S	Unknown	20 Mg,Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Apo-Leflunomide	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Plaquenil	S	Oral	2 Df, Qd	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	10 Mg, Qd	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	10 Mg, Qd	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	2 Df, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	16227027	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP012150		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State;	Acetaminophen			S	Unknown	Unk		Apotex

Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Chlorhexidine	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Trimethoprim/Sulfamethoxazole	S	Unknown	Unk	Apotex
	Oxycodone	S	Unknown	Unk	Apotex
	Oxycodone/Acetaminophen	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Abatacept	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Weeks (Solution For Infusion)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752 Milligram, One Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram, Q.I.W	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram, Q.M.T.	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Oxycodone Hcl Contrlled	S	Unknown	Unk	Not Reported

Release				
Periogard	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Periarticular		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	17.857 Mg, Qd	Not Reported
Orencia	S	Subcutaneous	125 Milligram, Q.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Q.Wk.	Not Reported
Chloraprep One Step	S	Topical	Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	S	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Arava	C	Oral	20 Mg, Qd	Not Reported
Desogestrel And Ethinyl Estradiol	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Pantoloc /01263201/	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Plaquenil /00072602/	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Mg, Unk	Not Reported
Reactine /00884302/	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Marvelon 28	C	Unknown	Unk	Not Reported

Zopiclone	C	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Cetirizine Dihydrochloride	C	Unknown	Unk		Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk		Not Reported
Enbrel	C	Unknown	Unk		Not Reported
Paracetamol Codeine	C	Unknown	Unk		Not Reported
Tylenol No.1	C	Unknown	Unk		Not Reported
Tylenol With Codeine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	16815521	EXPEDITED (15-DAY)		CA, OT	AR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-220778			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	16830336	EXPEDITED (15-DAY)		OT	CA-ROCHE-2403358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Canada)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17144108	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2800982-00		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Blood Potassium Decreased; Blood Pressure Fluctuation; Chest Discomfort; Chest X-Ray Abnormal; Dental Caries; Fall; Glaucoma; Joint Swelling; Musculoskeletal Chest Pain; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Osteoarthritis; Pain; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture; Seasonal Allergy; Spinal Osteoarthritis; Therapeutic Response Shortened;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Folic			C	Unknown			Not Reported
	Eliquis			C				Not Reported
	Prilosec			C				Not Reported
	Zantac			C				Not Reported
	Losartan			C				Not Reported
	Flexeril			C				Not Reported

Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17146486	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191211370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Liver Injury; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Reactine[Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Reactine (Cetirizine Dihydrochloride)			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi Iv			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	4 Mg		Not Reported

Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral	Dose 25 Mg	Not Reported
Methotrexate	S	Intra-arterial		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous drip		Not Reported
Desoximetasone	S	Oral		Not Reported
Etanercept	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous		Not Reported
Sulfasalazine	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Cosentyx	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Cortisone Acetate	S	Topical		Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported

	Apo-Hydroxyquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Calcium /00060701/	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Quetiapine	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17219075	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39439		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Etanercept			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported

Methotrexate	S	Oral			Not Reported
Methotrexate	S	Oral			Not Reported
Plaquenil	S	Oral	Unknown		Not Reported
Plaquenil	S	Oral	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Sulfasalazine	S	Oral	Unknown		Not Reported
Actemra	S	Unknown	Unknown		Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Sodium Aurothiomalate	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17557583	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318935		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Condition Aggravated; Cough; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Headache; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance; Viral	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

Infection	Plaquenil /00072602/	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Actemra	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17558095	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316684		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

	Remicade	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17579767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327866		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Headache; Hepatotoxicity; Insomnia; Joint Swelling; Memory Impairment; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Methotrexate	S		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Oral	Not Reported
Infliximab	S	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Insulin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17594562	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332781		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling;	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17603176	EXPEDITED (15-DAY)		HO	NVSC2020CA086171		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	50 Mg, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk Unk, Unknown		Not Reported
	Morphine			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17605627	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17620886	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug	Kineret			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	2.5 Mg 1 Every 2 Weeks		Not Reported

Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17623406	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Respiratory Tract Infection; Rheumatoid Arthritis; Synovitis; Treatment Failure; X-Ray Abnormal	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	5 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	7 Months		Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Extended Release	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17623408	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342102		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankylosing Spondylitis; Anxiety; Arthralgia; Back Pain; Cardiac Discomfort; Depression; Drug Ineffective; Drug Intolerance; Emotional Disorder; Erosive Oesophagitis; Feeling Abnormal; Gastritis; Gastrooesophageal Reflux Disease; Musculoskeletal Pain; Myofascial Pain Syndrome; Neck Pain; Pain In Extremity; Vitamin D Decreased	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Simponi Iv			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Ergocalciferol			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rabeprazole			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Vitamin D /00107901/			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Calcium W/Colecalciferol		C	Oral	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Olmetec		C	Oral	Not Reported
	Calcium Carbonate		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17647577	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403510		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17713314	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428290		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Cimzia		S	Subcutaneous	Solution For Injection In Pre-Filled Syringe	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17730403	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Ineffective For Unapproved Indication; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported

Etanercept	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil (Hydroxychloroquine Phosphate)	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17835092	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528677		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection	Remicade			S	Intravenous (not			Not Reported

Site Reaction; Renal Impairment; Rheumatoid Arthritis; Throat Tightness			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Apo-Ibuprofen	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17920022	EXPEDITED (15-DAY)		HO	NVSC2020CA170797		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Dosage Form Not Specified)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17980761	EXPEDITED (15-DAY)		OT	CA-ACCORD-188180			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18118272	EXPEDITED (15-DAY)		OT	CA-ACCORD-193868		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown	Not Specified		Accord
	Mycophenolic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Gold/Gold Keratinate/Gold Monosulfide/Gold Trisulfide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Subcutaneous	1 Every 21 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Not Specified		Not Reported

	Plaquenil	S	Unknown			Not Reported
	Piroxicam	C	Unknown	Not Specified		Not Reported
	Prednisone	C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18130339	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP012155		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Apotex
	Toradol			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, 2 Every 2 Days		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18190515	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04884		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Off Label Use	Ceftriaxone	S	Unknown	Unk	Lupin
	Azithromycin	S	Unknown	Unk	Lupin
	Hydroxychloroquine	S	Unknown	Unk	Lupin
	Lisinopril	S	Unknown	Unk	Lupin
	Atorvastatin	C	Unknown	Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Losartan	C	Unknown	Unk	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Glipizide	C	Unknown	Unk	Not Reported
	Citalopram	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Folate	C	Unknown	Unk	Not Reported
	Fluticasone	C	Unknown	Unk	Not Reported
	Betamethasone	C	Topical	Unk	Not Reported
	Fluocinonide	C	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18204361	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200829387			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis;	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete	Leflunomide	S	Unknown	Not Reported
	Penicillin G /00000901/	S	Unknown	Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride	S	Unknown	Not Reported
	Cetirizine /00884302/	C	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported
	Lasix /00032601/	C	Unknown	Not Reported
	Montelukast	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Terbutaline Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18209629	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-044806		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Levofloxacin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Clarithromycin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18241837	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use In Unapproved Indication; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk Milligram		Not Reported

Methotrexate	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Alendronate Sodium;Alendronic Acid	S			Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Folic Acid	S			Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Prednisone	S		Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S		Unk	Not Reported
Tocilizumab	S		Unk	Not Reported
Actemra	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Fosamax	S		Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18242855	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020344455		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Sulfasalazine			S	Unknown	1000 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		150 Mg, 1x/Day		Not Reported
	Methotrexate			C		20 Mg, Weekly		Not Reported
	Prednisone			C		5 Mg, 3x/Day (Will Taper		Not Reported

			Dose)	
	Venlafaxine	C	75 Mg, Daily	Not Reported
	Pantoprazole	C	40 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18245770	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		25 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Weekly (Qw)		Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	Unk, Once Daily (Qd)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S				Not Reported
	Xeljanz			S		5 Milligram, 2x/Day (Bid)		Not Reported

Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
Cortisone Acetate	S		25 Milligram	Not Reported
Cortisone	S	Oral		Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Subcutaneous		Not Reported
Diclofenac Sodium	S			Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Paracetamol	S			Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S			Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Tocilizumab	S			Not Reported
Caffeine;Codeine;Paracetamol	C			Not Reported
Sulfasalazine	C			Not Reported
Tofacitinib Citrate	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported

	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C				Not Reported
	Salazopyrina	C				Not Reported
	Actemra	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18246014	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020035166		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		25 Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Golimumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	4 Milligram		Not Reported
	Hydrocortisone Sodium Succinate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	1 Dosage Form		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S		Unk		Not Reported

Xeljanz	S		5 Milligram	Not Reported
Alendronate Sodium;Alendronic Acid	S	Oral	Unk Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Subcutaneous	Unk	Not Reported
Diclofenac Sodium	S		Unk	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S		500 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Paracetamol	S		Unk	Not Reported
Phthalylsulfathiazole	S	Oral	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Prednisone	S	Oral	5 Milligram	Not Reported
Paracetamol/Cafeine/Codeine Mylan	C		Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S			Not Reported
Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		10 Milligram	Ucb
Fosamax	S			Not Reported

Apo-Hydroxyquine	S				Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram		Not Reported
Salazopyrin	C				Not Reported
Reactine [Cetirizine Hydrochloride]	S				Not Reported
Topicorte	S	Subcutaneous			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Sulfathalidine	S				Not Reported
Hydrocortisone	S	Oral			Not Reported
Atasol [Paracetamol]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18248563	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035174		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		25 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Golimumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	1 Dosage Form		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound			otherwise specified)		
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S		Unk	Not Reported
	Xeljanz	S		5 Milligram	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral	5 Milligram	Not Reported
	Alendronate Sodium;Alendronic Acid	S		Unk	Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Paracetamol	S		Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Tocilizumab	S			Not Reported
	Topicort [Desoximetasone]	S		Unk	Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram	Not Reported

Hydrocortisone	S	Oral	Unk		Not Reported
Salazopyrin	S		Unk		Not Reported
Leflunomide	S		Unk		Not Reported
Apo-Prednisone	S		Unk		Not Reported
Actemra	S		Unk		Not Reported
Fosamax	S	Oral	5 Milligram		Not Reported
Fosamax	S		Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Tofacitinib Citrate	C				Not Reported
Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18254035	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac	S		Unk	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Prednisone	S			Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Sulfasalazine	S		1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Tocilizumab	S	Topical		Not Reported
Apo-Prednisone	S		Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Actemra	S	Topical	Unk	Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18254899	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020035212		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Not Reported

Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tofacitinib	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S			Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S			Not Reported
	Phthalylsulfathiazole	S	Oral	1000 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Tofacitinib Citrate	S		5 Milligram, 2x/Day (Bid)	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Unk	Not Reported
Alendronic Acid	S	Oral	Unk	Not Reported
Paracetamol With Codeine Phosphate	C			Not Reported
Caffeine Citrate	C			Not Reported
Sulfasalazine	C			Not Reported
Salazopyrin	C			Not Reported
Atasol [Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18265118	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-047587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Maternal Exposure During	Alendronic Acid			S	Oral	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Pregnancy; Pain; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18265690	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-025876		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation;	Diclofenac			S	Unknown			Not Reported
	Topicort			S	Cutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Maternal Exposure During Pregnancy; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound			otherwise specified)	
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Chlorhexidine	S	Topical	Not Reported
	Chlorhexidine Gluconate Oral Rinse	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortison (Cortisone)	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira (Adalimumab)	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

Oxycodone	S	Unknown		Not Reported
Oxycodone	S	Unknown		Not Reported
Oxycodone Terephthalate	S	Unknown		Not Reported
Oxycodone-Acetaminophen	S	Unknown		Not Reported
Periogard Alcohol Free	S	Buccal		Not Reported
Plaquenil	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Pseudoephedrine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous;Frequuency: Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Atasol	C			Not Reported
Cetirizine	C			Not Reported
Desogestrel/Ethinyl Estradiol	C			Not Reported
Ibuprofen	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole	C			Not Reported
Salazopyrin	C			Not Reported
Tylenol	C			Not Reported
Tylenol With Codeine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18265964	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-260404		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Ciprofloxacin			S	Unknown	500 Milligram, Tid(For 4 Weeks)		Ranbaxy
	Clindamycin			S	Unknown	300 Milligram, Bid(For 4 Weeks)		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Daily		Ipca
	Methylprednisolone			S	Oral	1 Milligram/Kilogram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18265968	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-260599		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Myopathy Toxic; Respiratory Acidosis; Respiratory Failure	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Anakinra			C	Subcutaneous	100 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266240	EXPEDITED (15-DAY)		HO	CH-TEVA-2020-CH-1827279		68 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glucose-6-Phosphate Dehydrogenase Deficiency; Haemolysis; Off Label Use	Hydroxychloroquine			S	Unknown	Single Dose		Teva
	Amoxicillin W/Clavulanic Acid			S	Unknown			Teva
	Piperacillin Sodium W/Tazobactam Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266246	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-047590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Alendronic Acid			S	Oral	Unk		Aurobindo
	Adalimumab			S	Oral	40 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported

Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266275	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-20K-163-3557943-00		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Hypoaesthesia; Injection Site Pain; Intervertebral Disc Compression; Neck Pain; Neuropathy Peripheral; Post Procedural Complication; Post Procedural Infection; Retinal Injury; Spinal Decompression; Spinal Fusion Surgery; Spinal Operation; Vision Blurred	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266312	NON-EXPEDITED			US-ADVANZ PHARMA-202009008540			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction	Hydroxychloroquine			S		Unk		Concordia
	Venclexta			S		Unk		Not Reported
	Obinutuzumab			C		Unk		Not Reported

Methenamine	C	Unk	Not Reported
Nexium 24hr	C	Unk	Not Reported
Flexeril	C	Unk	Not Reported
Xanax	C	Unk	Not Reported
Advil	C	Unk	Not Reported
Entyvio	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266316	NON-EXPEDITED			US-ADVANZ PHARMA-202009008578			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266320	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202008008416			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266343	EXPEDITED (15-DAY)		OT	AU-IPCA LABORATORIES LIMITED-IPC-2020-AU-003045			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata; Retinal Toxicity; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266478	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-047586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Alendronic Acid			S	Oral	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Tofacitinib Citrate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266494	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-047648		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram,1 Every 1 Weeks		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	7.5 Milligram		Not Reported
	Tridural			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266577	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05943		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid (For 2 Doses)		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Azithromycin			C	Unknown			Not Reported
	Elvitegravir			C	Unknown	Unk		Not Reported
	Tenofovir Alafenamide			C	Unknown	Unk		Not Reported

Emtricitabine	C	Unknown	Unk		Not Reported
Ceftriaxone	C	Unknown	Unk		Not Reported
Cefdinir	C	Unknown	Unk		Not Reported
Cobicistat	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266587	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05944		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Lamivudine			C	Unknown	Unk		Not Reported
	Abacavir			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Dolutegravir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266795	EXPEDITED (15-DAY)		OT	NVSC2020CA096584		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin Sandoz			S	Unknown	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk Unk, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk Unk, Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis

	Rituximab	S	Unknown	Unk Unk, Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unknown	Not Reported
	Orencia	S	Unknown	125 Mg, Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown	Not Reported
	Sulfasalazine	S	Oral	Unk Unk, Unknown	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266804	EXPEDITED (15-DAY)		OT	NVSC2020CA247362		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Ciclosporin			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unknown		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw (1 Every 1 Week)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported

	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unknown	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18266845	EXPEDITED (15-DAY)		OT	NVSC2020CA247552		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Dizziness; Ear Discomfort; Erythema; Fatigue; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Muscle Spasms; Nausea; Rheumatoid Arthritis; Vomiting	Sandostatin Lar			S	Intramuscular	20 Mg, Unknown		Novartis
	Sandostatin Lar			S	Intramuscular	30 Mg, Qmo		Novartis
	Sandostatin Lar			S				Novartis
	Atorvastatin Calcium			S	Unknown	10 Mg, Qd		Not Reported
	Bisoprolol			S	Unknown	2.5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unknown		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267047	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202009008623			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endocarditis; Hepatic Enzyme Increased; Urinary Retention	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267052	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202009008631			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Loss Of Personal Independence In Daily Activities; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tooth Infection	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Qod		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Parenteral	25 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Naproxen			S	Unknown	375 Mg, Prn		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	100 Mg, Qd		Not Reported
	Prednisone			S	Unknown	5 Mg, Intermittent		Not Reported
	Enbrel			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Piperacillin & Tazobactam			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	10 Milligram, Qd		Not Reported
	Mycophenolic Acid			S	Unknown	2 Dosage Form, Qd		Apotex
	Ceftazidime			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	2 Dosage Form, Qd	Not Reported
Vancomycin	S	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Amiodarone Hydrochloride	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown		Not Reported
Eprex	C	Intravenous (not otherwise specified)	Unk	Not Reported
Escitalopram	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Insulin Lispro	C	Unknown	Unk	Not Reported
Januvia [Sitagliptin Phosphate]	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Piperacilina + Tazobactam	C	Unknown	Unk	Not Reported
Potassium Chloride	C	Unknown	Unk	Not Reported
Risedron	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	Unk	Not Reported
Slow K	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Ventoline [Salbutamol Sulfate]	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267340	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28200		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Etanercept		S	Unknown	Unknown	Not Reported
	Actemra		S	Unknown	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Arava		S	Unknown	Unknown	Not Reported
	Enbrel		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown	Unknown	Not Reported
	Xeljanz		S	Oral		Not Reported
	Folic Acid		C	Unknown	Unknown	Not Reported
	Ibuprofen		C	Unknown	Unknown	Not Reported
	Ketorolac		C	Unknown	Unknown	Not Reported
	Methotrexate		C	Unknown		Not Reported
	Naproxen		C	Unknown	Unknown	Not Reported
	Prednisone		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267443	EXPEDITED (15-DAY)		OT	CA-ACCORD-200345			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Not Specified		Accord
	Alendronate Sodium/Alendronic Acid			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Folic Acid	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Orencia	S	Unknown			Not Reported
Prednisone	S	Unknown	Not Specified		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Topicort	S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267448	EXPEDITED (15-DAY)		OT	CA-ACCORD-200110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Methotrexate			S	Unknown			Accord
	Adalimumab			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown	1 Every 6 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267676	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200904216			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness;	Simponi			S	Subcutaneous			Not Reported
	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported

Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Certolizumab Pegol	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Advair	C		Not Reported
	Allopurinol	C	Unknown	Not Reported
	Atrovent Hfa	C		Not Reported
	Codeine	C		Not Reported
	Cyclobenzaprine Hydrochloride	C		Not Reported
	Dilaudid	C		Not Reported
	Esomeprazole Magnesium Trihydrate	C		Not Reported
	Hydromorphone Hydrochloride	C		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Ibuprofen	C		Not Reported
	Leucovorin Calcium	C		Not Reported
	Sulfasalazine	C		Not Reported
	Ventolin Hfa	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267740	EXPEDITED (15-DAY)		OT	CA-SA-2020SA248641			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Exostosis; Gastrointestinal Disorder; Rheumatoid Nodule	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Leflunomide			S		10-20mg, Qd		Sanofi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Xeljanz	S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18268267	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-202009008626			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Hospitalisation; Hypersensitivity; Malaise; Pneumonia; Rash; Swelling	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	125 Mg, Weekly (Qw)		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly (Qw)		Not Reported
	Amlodipine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Tynelol			C		Unk		Not Reported
	Cannabis			C		Unk		Not Reported
	Ventoline [Salbutamol]			C		Unk		Not Reported
	Vitamin D [Ergocalciferol]			C		Unk		Not Reported
	Pariet			C		Unk		Not Reported
	Apo-Atenidone			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Rixadone			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported
	Artificial Tear			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18268345	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020351576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective For Unapproved Indication; Joint Swelling; Off Label Use; Pain	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Acetaminophen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18268524	NON-EXPEDITED			US-MYLANLABS-2020M1076823		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18268546	EXPEDITED (15-DAY)		OT	NVSC2020CA248613			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion	Diclofenac Sodium			S	Unknown	Unk Mg		Novartis
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 G		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported

Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Mg	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported

	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	25 Mg	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18268821	NON-EXPEDITED			US-PFIZER INC-2020353318		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18269071	EXPEDITED (15-DAY)		OT	NVSC2020CA248867			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue;	Cortison Acetate			S	Unknown	25 Mg		Not Reported
	Diclofenac			S	Unknown	50 Mg		Novartis
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	400 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	10 Mg	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	40 Mg	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg	Not Reported
	Sulfasalazine	S	Oral	1 G	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18269554	EXPEDITED (15-DAY)		HO, OT	CA-ASTRAZENECA-2020SF17100		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Esomeprazole			S	Oral			Astrazeneca
	Apo Prednisone			S	Unknown			Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Subcutaneous	25.0mg Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18269766	EXPEDITED (15-DAY)		HO	IN-MYLANLABS-2020M1078427		32 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis; Off Label Use; Tachycardia; Tachypnoea	Hydroxychloroquine			S	Unknown	800 Mg, First Dose 800 Mg On First Day, Second Dose 400 Mg After 1 Week, The Same Dose In 3 Week.		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, First Dose 800 Mg On First Day, Second Dose 400 Mg After 1 Week, The Same Dose In 3 Week.		Mylan
	Pyridostigmine			C	Unknown	Unk Unk, Prn, Stable On Pyridostigmine (Sos) Without Any Disease-Modifying ...		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18270133	EXPEDITED (15-DAY)		DE	PK-PFIZER INC-2020351856		45 YR	Male	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Once Daily		Pfizer
	Azithromycin			S				Pfizer
	Meropenem			S	Intravenous (not otherwise specified)	500 Mg, 8 Hourly		Pfizer
	Meropenem			S				Pfizer
	Hydroxychloroquine			S		400 Mg (Stat)		Not Reported
	Hydroxychloroquine			S		200 Mg, 12 Hourly		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg, Once Daily		Not Reported
	Enoxaparin			S				Not Reported
	Losartan			C		50 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18304671	DIRECT					70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Guillain-Barre Syndrome; Infection; Respiratory Tract Infection	Hydroxychloroquine			S				Not Reported
	Lopinavir-Ritonavir			S				Not Reported
	Azithromycin			S				Not Reported
	Immunoglobulins, Intravenous			S	Intravenous (not otherwise specified)		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18304737	DIRECT					70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastrointestinal Disorder; Off Label Use	Hydroxycholoroquine Sulphate-Bp			S			7 DAY	Not Reported
	Lopinavir			S				Not Reported
	Ritonavir			S				Not Reported
	Azithromycin			C				Not Reported
	Immunoglobulins, Intravenous			C	Intravenous (not otherwise specified)	Dose: 0.4g/Kg	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18306314	DIRECT					30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Transaminases Increased	Hydroxychloroquine			S			1 DAY	Not Reported
	Azithromycin			S				Not Reported
	Piperacillin-Tazobactam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18306324	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Assist Device Therapy; Multi-Organ Disorder; Product Use In Unapproved Indication; Product Use Issue; Suspected Covid-19	Hydroxychloroquine Sulfate			S				Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18306659	DIRECT		OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Headache; Myalgia; Product Use In Unapproved Indication; Product Use Issue; Pyrexia	Lopinavir-Ritonavir			S			3 DAY	Not Reported
	Hydroxychloroquine			S			10 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18306810	DIRECT					82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Atrial	Lopinavir-Ritonavir			S				Not Reported

Fibrillation; Atrioventricular Block; Continuous Haemodiafiltration; Product Use In Unapproved Indication; Product Use Issue; Renal Replacement Therapy; Thrombocytopenia	Tocilizumab	S	Other Frequency:Over Two Days;Other Route:Iv	Not Reported
	Hydroxychloroquine	S		Not Reported
	Azithromycin	S		Not Reported
	Hydrocortisone	S	Other Route:Iv	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	11308664	NON-EXPEDITED		OT	CA-AMGEN-CANSP2011017837		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Apo Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported

Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Naprosyn	C	Unknown	Unk Unk, As Required	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Asa	C	Unknown	81 Milligram	Not Reported
Asa	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, As Required	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Lozide	C	Unknown	Unk	Not Reported
Lantus	C	Unknown	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported

	Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Milligram	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D3	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	12776522	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-024854		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	40 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	4 Milligram		Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	250 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not	1 G, Unk		Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	50 Mg, Qmo	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Prevacid	C	Unknown	30 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	50 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	12914309	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091711		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Q2mo		Bristol Myers Squibb
	Orencia			S	Intravenous drip	250 Milligram, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular			Bristol Myers Squibb
	Triamcinolone Acetonide			S				Bristol Myers Squibb
	Triamcinolone Acetonide			S				Bristol Myers Squibb
	Triamcinolone Acetonide			S				Bristol Myers Squibb
	Triamcinolone			S	Subcutaneous	25 Milligram, Q2wk		Not Reported

Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Triamcinolone	S			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
	Infliximab	S	Unknown	3 Milligram/Kilogram, Q6wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Q6wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	50 Milligram	Not Reported
	Prednisone	S	Oral	50 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not	280 Milligram, Bid	Not Reported

		otherwise specified)		
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	50 Milligram	Not Reported
Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Enbrel	S	Unknown	1.5 Milligram, Qwk	Not Reported
Enbrel	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
Enbrel	S	Subcutaneous	25 Milligram	Not Reported
Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Apo-Hydroxyquine	S	Oral	5 Mg, Qd	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Kineret	S			Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S			Not Reported
Apo-Naproxen	S	Oral	5 Milligram, Qd	Not Reported
Apo-Naproxen	S	Oral	3 Milligram, Qd	Not Reported
Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported

Apo-Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
Apo Triamcinolone Aq	S	Unknown		Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Etanercept	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Etanercept	S	Subcutaneous	12.5 Milligram	Not Reported
Gamastan	S	Intramuscular	70 Gram	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	Unk	Not Reported
Folic Acid	C	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Other	Unk	Not Reported
Triamcinolone Hexacetonide	S			Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Naproxen Sodium	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	13628306	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170602932		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Intentional Product Use Issue; Lymphoma;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Zostavax	S	Unknown	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Zostavax	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not	Not Reported

			otherwise specified)	
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Diclofenac	C	Oral	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Cortisone	C	Unknown	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Voltaren /00372302/	C		Not Reported
	Cortisone	C	Subcutaneous	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Diclofenac	C	Subcutaneous	Not Reported
	Diclofenac	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	15801002	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-1098		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema; Herpes Zoster; Hypoaesthesia; Immunosuppression; Infection; Influenza; Mouth Ulceration; Pyrexia; Rheumatoid Arthritis; Rhinorrhoea; Tachycardia; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	15851869	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634031-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	15935379	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2656919-00		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Erelzi [Etanercept]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	16162286	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2733052-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Contraindicated Product Administered; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	16686320	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21297		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Walking Aid User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Infliximab	S	Unknown	Unknown	Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown, Solution Intravenous	Not Reported

Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Oral			Not Reported
Xeljanz	S	Unknown	Unknown		Not Reported
Apo-Prednisone	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Plaquenil	S	Oral			Not Reported
Plaquenil	S	Oral			Not Reported
Atorvastatin	C	Unknown			Not Reported
Atorvastatin	C	Unknown	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown	Unknown		Not Reported
Pantoloc	C	Unknown	Enteric-Coated		Not Reported
Pantoloc	C	Unknown			Not Reported
Pantoloc	C	Unknown	Unknown		Not Reported
Pantoprazole	C	Unknown	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unknown		Not Reported
Plaquenil	C	Oral			Not Reported
Plaquenil	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	16923495	EXPEDITED (15-DAY)		OT	CA-ROCHE-2428507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Rituxan			S	Intravenous (not			Not Reported

Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound			otherwise specified)	
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Canada)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17216520	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-107050		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Blood Cholesterol Increased; Contraindicated Product	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Once A Day	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

Sulfasalazine	S	Oral	1000 Milligram		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfathalidine	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Diclofenac	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17566309	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320884		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17580229	EXPEDITED (15-DAY)		DS, HO, OT	CA-BIOVITRUM-2020CA1335		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthritis; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Operation; Gastroenteritis Viral; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypertension; Hypocalcaemia; Hypokalaemia; Hypotension; Ill-Defined Disorder; Immunodeficiency; Infection; Intentional Product Use Issue; Joint Destruction; Joint Swelling; Limb Discomfort; Limb Discomfort; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Nausea; Nodule; Obesity; Off Label Use; Pleural Effusion; Pneumonia;	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Oral			Not Reported
	Anakinra			S	Subcutaneous	50 Mg		Not Reported
	Actemra			S	Subcutaneous	100 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	20 Mg		Not Reported

Polyarthritis; Psoriasis; Pulmonary Fibrosis; Pyrexia; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Treatment Failure; Vomiting; Wheelchair User	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Mg	Not Reported
	Risedronate Sodium	S	Oral		Not Reported
	Risedronate Sodium	S	Unknown	16.35	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gm	Not Reported
	Rituxan	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip	1 Gm	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Risedronate	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Risedronic Acid	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral	1.3 Mg	Not Reported
Prednisone	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Risedronate	C	Unknown		Not Reported
Hydroxychloroquine Sulfate	C			Not Reported
Hydroxychloroquine Sulfate	C			Not Reported
Xeljanz	C	Oral		Not Reported
Methotrexate	C	Unknown	Dose: 17.5 Mg	Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17744110	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS-2020M1043359		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Pyrexia; Respiratory Disorder	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Mylan
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Mylan
	Hydroxychloroquine Sulfate			S	Unknown	1200 Milligram, Qd		Mylan
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Mylan
	Omeprazole			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Mylan
	Omeprazole			S	Intravenous (not otherwise specified)	40 Milligram, Qd		Mylan
	Loxen /00890702/			S	Intravenous (not otherwise specified)	30 Milligram, Qd		Mylan
	Movicol /01749801/			S	Other	2 Dosage Form Bag		Mylan
	Movicol /01749801/			S	Other	2 Df Bag		Mylan
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Mylan
	Omeprazol 1 A Pharma			C	Other	20 Mg, Qd		Mylan
	Paracetamol			C	Other	4 G, Qd		Mylan
	Paracetamol			C				Mylan
	Diffu K			C	Unknown	3.6 Gram, Qd		Mylan
	Lasilix /00032601/			C	Other	30 Milligram, Qd		Mylan
	Doliprane			C		Unk		Mylan
	Doliprane			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17746494	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114129			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine			S				Not Reported

Ineffective For Unapproved Indication; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Hydrochloride/Pseudoephedrine Hydrochloride				
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S			Not Reported
	Sulfasalazine	S	Subcutaneous	500 Mg	Not Reported
	Arava	S	Oral		Sanofi
	Hydroxychloroquine	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Methotrexate	S	Intra-arterial	25 Mg	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S			Sanofi
	Prednisone	S			Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported

	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17844794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609327		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Drug Intolerance; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Irritable Bowel Syndrome; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported
	Lyrica			C	Unknown			Not Reported
	Sulfasalazin			C	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Valsartan			C				Not Reported
	Wellbutrin			C				Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17956169	EXPEDITED (15-DAY)		OT	CA-ACCORD-185855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Intra-arterial			Accord
	Hydroxychloroquine			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Prednisone			S				Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S				Not Reported
	Cetirizine/Pseudoephedrine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Alendronic Acid			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Pseudoephedrine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Tofacitinib			C				Not Reported
	Tofacitinib			C				Not Reported
	Methotrexate			S	Oral			Accord
	Methotrexate			S	Unknown			Accord

	Folic Acid	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	17996608	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054402		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18013426	EXPEDITED (15-DAY)		OT	CA-ACCORD-189563		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Subcutaneous	Not Specified		Not Reported

Pneumonia; Pulmonary Embolism	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Calcium Carbonate/Colecalciferol	C			Not Reported
	Hydrocortisone	C		Not Specified	Not Reported
	Pantoloc	C			Not Reported
	Prednisone	C		Not Specified	Not Reported
	Tylenol	C		Arthritis Pain 8h 2 Every 1 Days	Not Reported
	Xarelto	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18106185	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2020M1068148		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acanthosis; Acute Generalised Exanthematous Pustulosis; Eczema; Epidermal Necrosis; Erythema Multiforme; Lymphocytic Infiltration; Off Label Use; Pustule; Rash; Rash Erythematous; Rash Pruritic; Rash Pustular; Skin Exfoliation; Target Skin Lesion	Lopinavir/Ritonavir			S		200/50mg 2 Tables		Mylan
	Lopinavir/Ritonavir			S				Mylan
	Hydroxychloroquine /00072603/			S	Unknown	200 Mg, Bid (12 Hours)		Mylan
	Hydroxychloroquine /00072603/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18238797	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200843913		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Nystatin	S	Unknown	Not Reported
	Nystatin	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Indometacin	C		Not Reported
	Prednisone	C		Not Reported
	Tramadol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18242569	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035281			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Methotrexate			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported

Failure	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Alendronate Sodium;Alendronic Acid	S			Not Reported
	Cortisone Acetate	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S		40 Milligram	Not Reported
	Prednisone	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
	Tocilizumab	S			Not Reported
	Diclofenac	C		50 Milligram	Not Reported
	Sulfasalazine	C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
	Actemra	S		Unk	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Pseudoephedrine Hcl	S		Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Apo-Prednisone	S		Unk	Not Reported

	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Salazopyrin		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18243430	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alendronate Sodium;Alendronic Acid			S	Oral			Not Reported
	Cortisone Acetate			S		25 Milligram		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Folic Acid			S		5 Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sulfasalazine	S		500 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Apo-Prednisone	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Actemra	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18243614	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035220		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram, Once Daily (Qd)		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Cortisone Acetate			S	Oral			Not Reported

Cortisone Acetate	S			Not Reported
Desoximetasone	S	Subcutaneous		Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Diclofenac Sodium	S			Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S		500 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, 2x/Day (Bid)	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S		5 Milligram	Not Reported
Prednisone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Tocilizumab	S			Not Reported
Leflunomide	S		Unk	Not Reported
Actemra	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S		Unk	Not Reported
Atasol [Paracetamol]	C		Unk	Not Reported
Paracetamol	C			Not Reported
Caffeine Citrate	C			Not Reported

	Codeine Phosphate	C	Not Reported
	Leflunomide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18244129	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020035216		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S				Not Reported
	Alendronate Sodium;Alendronic Acid			S	Oral			Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported

Diclofenac Sodium	S			Not Reported
Flumetasone Pivalate	S	Subcutaneous		Not Reported
Folic Acid	S		5 Milligram	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine	S			Not Reported
Phthalylsulfathiazole	S	Oral	1000 Milligram	Not Reported
Phthalylsulfathiazole	S	Oral	500 Unk	Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S			Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Tofacitinib Citrate	S		5 Milligram	Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Hydroxyquine	S		9999	Not Reported
Orencia	S	Subcutaneous		Not Reported
Topicorten	S	Cutaneous		Not Reported
Diclofenac	S			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Apo-Folic Acid	S		5 Milligram	Not Reported
Fosamax	S	Oral		Not Reported
Actemra	S	Subcutaneous	Pre Filled Syringe	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18246139	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2020035146		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain;	Cimzia			S	Subcutaneous			Not Reported

Abdominal Pain Upper; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Discomfort; Dizziness; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Fibromyalgia; General Physical Health Deterioration; Glossodynia; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Nausea; Oedema; Off Label Use; Pemphigus; Pericarditis; Prescribed Overdose; Product Use In Unapproved Indication; Product Use Issue; Product Used For Unknown Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus	Cimzia	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S		Unk	Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Cetirizine Hydrochloride	S		25 Milligram	Not Reported
	Cetirizine Hydrochloride	S		25 Milligram	Not Reported
	Cetirizine Hydrochloride	S		10 Milligram	Not Reported
	Cetirizine Hydrochloride	S		10 Milligram, Once Daily (Qd)	Not Reported
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Cetirizine Hydrochloride	S		10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		10 Milligram	Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		10 Milligram	Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		25 Milligram	Ucb
	Arava	S		Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk Milligram	Not Reported
	Golimumab	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Cetirizine Hydrochloride;Phenylephrine Hydrochloride	S		10 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S		25 Milligram	Not Reported
	Methotrexate	S		20 Milligram	Not Reported

Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; Wheezing; Wound	Methotrexate	S	Intra-arterial	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk Milligram	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S		Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S			Not Reported
	Xeljanz	S		5 Milligram	Not Reported
	Xeljanz	S		Unk	Not Reported
	Alendronate Sodium;Alendronic Acid	S		Unk	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral	Unk	Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	S			Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Etanercept	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported

Folic Acid	S		5 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Folic Acid	S		500 Milligram	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Paracetamol	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		40 Milligram, Once Daily (Qd)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Topicort [Desoximetasone]	S		Unk	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Prednisone	S		Unk	Not Reported
Sulfasalazine	S		1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		1 Gram, 2x/Day (Bid)	Not Reported
Actemra	S		Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S		400 Milligram, Once Daily (Qd)	Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Unk	Not Reported
Apo-Folic Acid	S		15 Milligram	Not Reported

	Naproxen Sodium	S	500 Milligram, 2x/Day (Bid)	Not Reported
	Diclofenac Sodium	S	Unk	Not Reported
	Xeljanz	S	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unk Unk, 2x/Day (Bid)	Not Reported
	Tofacitinib	C		Not Reported
	Prinivil	C		Not Reported
	Colecalciferol	C		Not Reported
	Acetaminophen;Codeine Phosphate	C		Not Reported
	Atasol [Paracetamol]	C		Not Reported
	Zyrtec [Cetirizine Hydrochloride]	C		Not Reported
	Ibuprofen Sodium	C		Not Reported
	Lisinopril Anhydrous	C		Not Reported
	Sulfasalazine	C		Not Reported
	Lisinopril Dihydrate	C		Not Reported
	Paracetamol/Cafeine/Codeine Mylan	C		Not Reported
	Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18246179	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035163		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S				Not Reported

Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Hydrocortisone Acetate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S	Oral	40 Milligram	Not Reported
	Prednisone	S			Not Reported
	Prednisone	S			Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

	Sulfasalazine	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
	Diclofenac	C			Not Reported
	Sulfasalazine	C			Not Reported
	Fosamax	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Infusion, Solution	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Apo-Prednisone	S			Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Sulfasalazine	S		500 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	S		10 Milligram	Not Reported
	Actemra	S	Subcutaneous	Pre-Filled Syringe	Not Reported
	Salazopyrin	C			Not Reported
	Sulfathalidine	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18246180	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035179		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		25 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Golimumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydrocortisone			S	Oral			Not Reported

Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	1 Dosage Form	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S		Unk	Not Reported
	Xeljanz	S		5 Milligram	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Paracetamol	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S		Unk	Not Reported
	Caffeine;Codeine;Paracetamol	C			Not Reported
	Sulfasalazine	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18246293	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020035159			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram, Once Daily (Qd)		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram, Once Daily (Qd)		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S		10 Milligram		Not Reported
	Tofacitinib			S		5 Milligram, 2x/Day (Bid)		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram, Once Daily (Qd)		Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Diclofenac	S		Unk	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S	Oral	2000 Milligram	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S			Not Reported
Prednisone	S			Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Tofacitinib Citrate	S		10 Milligram	Not Reported
Tofacitinib Citrate	S		5 Milligram, 2x/Day (Bid)	Not Reported
Caffeine;Codeine;Paracetamol	C			Not Reported
Sulfasalazine	C			Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Atasol [Paracetamol]	C			Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Salazopyrin	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18246295	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020035156		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Cimzia			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram 2 Times A Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Alendronate Sodium;Alendronic Acid			S	Oral	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported

Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Desoximetasone	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Diclofenac	S			Not Reported
Folic Acid	S		1 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Paracetamol	S		10 Milligram	Not Reported
Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S		Unk	Not Reported
Tofacitinib Citrate	S		5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	C			Not Reported
Ascorbic Acid	C			Not Reported
Ergocalciferol	C			Not Reported
Glucosamine	C			Not Reported
Lansoprazole	C			Not Reported
Lorazepam	C			Not Reported
Salmon Oil	C			Not Reported
Sulfasalazine	C			Not Reported
Vitamin D [Vitamin D Nos]	C			Not Reported
Topicorte	S	Subcutaneous		Not Reported
Fosamax	S	Oral		Not Reported
Actemra	S			Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Ativan	C			Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		200 Milligram, 2x/Day (Bid)	Not Reported
Salazopyrin	C			Not Reported

	Apo-Prednisone			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18246498	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035243		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		25 Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S	Oral	1 Dosage Form		Not Reported
	Methotrexate			S	Oral	25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S		5 Milligram, Once Daily (Qd)		Not Reported
	Adalimumab			S		Unk		Not Reported
	Cortisone Acetate			S		25 Milligram		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Stelara			S		Unk		Not Reported

Alendronate Sodium;Alendronic Acid	S		Unk	Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported
Golimumab	S		Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Diclofenac Sodium	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Paracetamol	S		Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Prednisone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Tocilizumab	S		Unk	Not Reported
Paracetamol With Codeine Phosphate	C			Not Reported
Caffeine Citrate	C			Not Reported
Sulfasalazine	C			Not Reported
Tofacitinib Citrate	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Atasol [Paracetamol]	C			Not Reported
Salazopyrin	C			Not Reported
Orencia	S	Subcutaneous		Not Reported
Hydrocortisone	S	Oral		Not Reported
Topicorte	S			Not Reported
Fosamax	S	Oral		Not Reported
Apo-Prednisone	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18248382	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035260		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		25 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk Unk, Once Daily (Qd)		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S				Not Reported
	Xeljanz			S		5 Milligram		Not Reported
	Alendronate Sodium;Alendronic Acid			S	Oral			Not Reported
	Cortisone Acetate			S		25 Milligram		Not Reported
	Cortisone Acetate			S	Oral			Not Reported

Desoximetasone	S	Oral		Not Reported
Desoximetasone	S			Not Reported
Desoximetasone	S	Subcutaneous		Not Reported
Diclofenac Sodium	S			Not Reported
Folic Acid	S		5 Milligram	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported
Hydrocortisone Acetate	S			Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral	2 Gram, Once Daily (Qd)	Not Reported
Fosamax	S		Unk	Not Reported
Fosamax	S		Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Acetaminophen	S		Unk	Not Reported
Sulfasalazine	S		50 Milligram	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S			Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Subcutaneous	2 Gram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S		400 Milligram, Once Daily	Not Reported

			(Qd)	
	Xeljanz	S	10 Milligram	Not Reported
	Actemra	S	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Leflunomide	S		Not Reported
	Atasol [Paracetamol]	C		Not Reported
	Salazopyrin	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Codeine Phosphate	C		Not Reported
	Caffeine Citrate	C		Not Reported
	Paracetamol	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18248465	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035248		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate [Methotrexate Sodium]			S				Not Reported
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)		
Simponi	S	Subcutaneous		Not Reported
Alendronate Sodium;Alendronic Acid	S			Not Reported
Cortisone Acetate	S			Not Reported
Desoximetasone	S	Oral		Not Reported
Folic Acid	S		5 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S		40 Milligram	Not Reported
Prednisone	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Tocilizumab	S			Not Reported
Diclofenac	C		50 Milligram	Not Reported
Diclofenac Potassium	C		50 Milligram	Not Reported
Diclofenac Sodium	C		50 Milligram	Not Reported
Pseudoephedrine Hcl	S			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18250028	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035130		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Infusion	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported

Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cetirizine Hydrochloride	S		10 Milligram	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported
	Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	40 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate Sodium	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S	Oral	40 Milligram	Not Reported

Prednisone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S			Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, 2x/Day (Bid)	Not Reported
Sulfathalidine	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Sulfasalazine	S	Oral	Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
Cortisone Acetate	S		Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	100 Milligram, 2x/Day (Bid)	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Diclofenac Potassium	C			Not Reported
Diclofenac	C		50 Milligram	Not Reported
Diclofenac Na	C		50 Milligram	Not Reported
Sulfasalazine	C			Not Reported
Salazopyrin	C			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18254067	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035245			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate [Methotrexate Sodium]			S		20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alendronate Sodium			S				Not Reported
	Cortisone Acetate			S				Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram		Not Reported
	Tocilizumab			S				Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Sulfathalidine	S			Not Reported
	Salazopyrin	C		Unk	Not Reported
	Diclofenac	C			Not Reported
	Diclofenac	C	Unknown		Not Reported
	Diclofenac Potassium	C			Not Reported
	Diclofenac Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18269679	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-047589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Alendronic Acid			S	Oral	Unk		Aurobindo
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milliliter, Once A Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18270445	EXPEDITED (15-DAY)		HO, OT	IN-LUPIN PHARMACEUTICALS INC.-2020-05954		32 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis; Off Label Use; Tachycardia; Tachypnoea	Hydroxychloroquine			S	Unknown	800 Milligram		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram		Lupin
	Pyridostigmine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18271534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2673684		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Mobicox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18271658	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-047606		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Exposure During Pregnancy; Inferior Vena Cava Syndrome; Off Label Use; Septic Shock	Dexamethasone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18271999	EXPEDITED (15-DAY)		OT	NVSC2020CA248610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling;	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	25 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported

Synovitis; Systemic Lupus Erythematosus; Wound	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Cortison	S	Unknown	Unk	Not Reported
	Caffeine Citrate	C	Unknown	Unk	Not Reported
	Paracetamol Codeine	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272024	EXPEDITED (15-DAY)		OT	CA-ACCORD-200854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Parenteral			Accord
	Arava			S				Not Reported
	Orencia			S		1 Every 1 Weeks		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	C		Not Reported
	Methotrexate	S	Subcutaneous	Accord
	Methotrexate	S	Oral	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272281	EXPEDITED (15-DAY)		OT	CA-ACCORD-200586		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Accord
	Pregabalin			S	Oral	1 Every 1 Days		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Piroxicam			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown	Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Teva Mycophenolate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272344	EXPEDITED (15-DAY)		OT	CA-ACCORD-200843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Adalimumab			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Rituximab			S	Intravenous drip	1 Every 6 Months		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272351	EXPEDITED (15-DAY)		OT	CA-ACCORD-200841			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dactylitis; Drug Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Azathioprine			S	Unknown			Not Reported
	Cosentyx			S	Unknown	1 Every 1 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			C	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272398	EXPEDITED (15-DAY)		OT	NVSC2020CA250945		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Pain In Extremity; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Unknown	Unk		Novartis
	Methotrexate Disodium			S	Subcutaneous	25 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	08 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulphate			C	Oral	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulphate			C	Unknown	Unk		Not Reported
	Arava			C	Oral	20 Mg, Qd		Not Reported
	Cimzia			C	Subcutaneous	200 Mg, Q2w		Not Reported
	Orencia			C	Unknown	75 Mg, Qmo		Not Reported

	Risedronate	C	Oral	350 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272598	EXPEDITED (15-DAY)		OT	NVSC2020CA247449		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial Neuralgia; Fatigue; Groin Pain; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Labyrinthitis; Muscle Spasms; Nausea; Rheumatoid Arthritis; Visual Impairment; Vomiting	Sandostatin Lar			S	Intramuscular	30.0 Mg, Qmo		Novartis
	Sandostatin Lar			S	Intramuscular	30.0 Mg, Qmo		Novartis
	Sandostatin Lar			S				Novartis
	Sandostatin			S	Subcutaneous	Unk		Novartis
	Bisoprolol			S	Unknown	2.5 Mg, Bid		Not Reported
	Atorvastatin Calcium			S	Unknown	10.0 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5.0 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273136	EXPEDITED (15-DAY)		HO, LT, OT	JP-APPCO PHARMA LLC-2090792		17 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Circulatory Collapse; Grunting; Hypokalaemia; Hypotension; Intentional Overdose; Moaning; Muscular Weakness; Paraesthesia; Toxicity To Various Agents; Ventricular Extrasystoles; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Mycophenolate Mofetil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273477	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1078703		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Torsade De Pointes	Hydroxychloroquine			S	Oral	400 Milligram, Bid On Day 1		Mylan
	Hydroxychloroquine			S	Oral	200 Milligram, Bid For 4 Days		Mylan
	Azithromycin			S	Oral	500 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273524	EXPEDITED (15-DAY)		HO, OT	IN-APPCO PHARMA LLC-2090797		32 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273559	EXPEDITED (15-DAY)		HO, LT, OT	US-APPCO PHARMA LLC-2090798		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragm Muscle Weakness; Encephalopathy; Hiatus Hernia; Incorrect Product Administration Duration; Myopathy Toxic; Pneumothorax; Respiratory Failure	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Hydrocortisone			S	Unknown			Not Reported
	Anakinra			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273636	EXPEDITED (15-DAY)		OT	NVSC2020CA252155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Hydrocortisone Acetate			S	Oral	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	40 Mg		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

				otherwise specified)			
	Orencia		S	Subcutaneous	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi		S	Subcutaneous	Unk		Not Reported
	Alendronate Sodium		S	Oral	Unk		Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk		Not Reported
	Diclofenac		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273830	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Atorvastatin Calcium			C	Unknown	Unknown		Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18274073	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200919764		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Off Label Use; Product Use In Unapproved Indication; Renal Mass; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Medroxyprogesterone Acetate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Cyclosporine			C	Unknown			Not Reported
	Depo-Provera			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18274714	NON-EXPEDITED			US-ABBVIE-20P-163-3443477-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Intolerance; Dry Eye; Dry Throat; Ear Pain; Fatigue; Feeling Abnormal; Gastric Disorder; Gastrointestinal Disorder; General Physical Condition Abnormal; Hypersensitivity; Immunodeficiency; Osteoarthritis; Psoriatic Arthropathy; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Thirst; Vertigo	Rinvoq	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18274754	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075311			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pain; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	400 Milligram, Qwk		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18275261	EXPEDITED (15-DAY)		OT	NVSC2020CA252131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Topical	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Stelara	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	5 Mg	Not Reported
	Sulfasalazine	S	Oral	2 G	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18275946	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20200924790		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Ipratropium Bromide W/Salbutamol Sulfate			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec /00661201/			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18276036	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200923093		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Tylenol			S	Unknown			Not Reported
	Simponi Iv			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Asa			S	Unknown			Not Reported
	Calcium /00060701/			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Vitamin D /00107901/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18281753	DIRECT					36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Hydroxychloroquine			S		Other Dose:400-600mg ;	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18311845	DIRECT					70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Lopinavir			S				Not Reported

Device Use Issue; Liver Injury; Product Use Issue; Respiratory Disorder	Ritonavir	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Remdesivir	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	11203581	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015010325		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Vomiting; Wound	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Subcutaneous	20 - 25 Mg, Qwk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Rituxan			S	Unknown	1 Gram, 1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Unknown	50 Milligram, Q4wk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Orencia			S	Subcutaneous	150 Milligram, Qwk		Not Reported
	Orencia			S	Subcutaneous	150 Gram		Not Reported
	Orencia			S	Subcutaneous	150 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported

Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	50 Milligram	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Naprosyn	C	Unknown	500 Milligram, Bid	Not Reported
Naprosyn	C	Unknown	50 Milligram	Not Reported
Celebrex	C	Unknown	200 Milligram	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	11233611	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015064980		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Amgen
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	7 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	1 Milliliter, Qwk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo Mycophenolate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	1 Milliliter, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	17 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	11752885	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015121181		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise;	Enbrel			S	Subcutaneous	Unk		Amgen
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Indocid			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Indomethacin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Gold (198 Au)	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25,Unk, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
	Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	100 Milligram	Not Reported

	Folic Acid	S	Oral	Unk, Qwk	Not Reported
	Folic Acid	S	Oral	5 Milligram, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
	Cymbalta	C	Oral	30 Milligram, 30 Mg, Qd At Nights	Not Reported
	B Complex [Vitamin B Complex]	C		Unk	Not Reported
	Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported
	Fish Oil	C		Unk	Not Reported
	Advil [Ibuprofen]	C			Not Reported
	Demerol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	12072431	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016015699		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	12172769	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016029473		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
Adverse Reaction; Arthralgia; Arthropathy;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis;	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q4wk		Not Reported
	Actemra			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Not Reported
	Orencia			S	Subcutaneous	Unk, Qwk		Not Reported
	Orencia			S	Vaginal	750 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q3wk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram		Not Reported
	Sulfasalazine			S	Unknown	2.5 Milligram, Qd		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	750 Milligram, Qmo		Not Reported

Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Subcutaneous	7.5-12.5 Milligram, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Gabapentin	S	Oral	100 Milligram, Q2wk	Not Reported
	Omega-3	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram 1-3 Tabs, Qhs	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
	Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
	Vitamin D	C		400 Unit, Qd	Not Reported
	Actonel	C		36 Mg, Qwk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, (Every Four Weeks)	Not Reported
	Aclasta	C		750 Milligram, Qmo	Not Reported

Aclasta	C	Intravenous (not otherwise specified)	488 Unk	Not Reported
Calcium	C		Unk	Not Reported
Genteal	C		3m Use As Directed	Not Reported
Tylenol	C	Oral	500 Mg 2 Tabs, Od	Not Reported
Nexium	C		40 Milligram One Tab, Bid	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qhs	Not Reported
Nasonex	C		2 Sprays Per Nostrils, Bid	Not Reported
Percocet	C		1 Tab, 4-6h Prn For Pain	Not Reported
Lomotil	C		2.5 Milligram, 3-4 Times/Day	Not Reported
Lomotil	C		2.5 Milligram, Qd	Not Reported
Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk, Q2wk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C		Unk, Qd	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Unk	Not Reported
Trazodone	C		Unk; 1000 Milligram, Qd	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Loperamide Hydrochloride	C		2.5 Milligram	Not Reported
Ergocalciferol	C		400 International Unit, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Fergon	C		300 Milligram, Qd	Not Reported

Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported
Acetaminophen	C		Unk	Not Reported
Zoledronic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	12224346	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015029495		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Back Pain; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Bid		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram		Amgen
	Actemra			S	Intravenous (not	Unk		Not Reported

Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Oral Pain; Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete			otherwise specified)		
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Unknown	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Orencia	S	Unknown	Unk Unk, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram, Qwk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported

Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	4.0 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Milligram	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Unknown	20 Milligram	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Doxycycline Hyclate	S	Unknown	50 Milligram	Not Reported
Prednisone	C	Oral	5 Milligram, Qd	Not Reported
Benadryl	C	Unknown	Unk Unk, As Necessary	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Lasix	C		40 Milligram, Tid	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex	C	Unknown	Unk, As Necessary	Not Reported
Enablex	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 Gram, Qd At Bedtime	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 Gram	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk Unk, Bid	Not Reported
Omnaris	C	Unknown	Unk	Not Reported

Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Cortisone	C	Intra-arterial	Unk	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Dilaudid	C	Unknown	4 Milligram, Q6h	Not Reported
Dilaudid	C		4 Milligram	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Kineret	C		100 Milligram	Not Reported
Furosemide	C	Unknown	40 Milligram, Tid	Not Reported
Furosemide	C		40 Milligram, 3 Times/Wk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk Unk, As Required	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk Unk, As Necessary	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
Norflex	C	Unknown	Unk Unk, Bid	Not Reported
Norflex	C		Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported

Kadian	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Milligram	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Plantago Ovata	C	Unknown	Unk	Not Reported
Dyclonine Hydrochloride	C		Unk	Not Reported
Orphenadrine	C	Unknown	1 Dosage Form, Bid	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram	Not Reported
Pantoloc [Pantoprazole]	C			Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qd	Not Reported
Methotrexate	C	Vaginal	25 Milligram, 4 Times/Wk	Not Reported
Methotrexate	C	Unknown	25 Milligram, 4 Times/Wk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	12312494	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016039095		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	592 Milligram, Q4wk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	10 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk, Qwk		Not Reported
	Arava			S	Unknown	Unk, Qwk		Not Reported
	Arava			S	Intravenous (not otherwise specified)	592 Milligram, Q4wk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	15 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Remicade	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Cortisone	C		Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Infliximab	C	Unknown	300 Milligram	Not Reported
Infliximab	C	Unknown	300 Milligram, Q8wk	Not Reported
Infliximab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	12337536	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055447		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bedridden; Crying; Drug Ineffective	Enbrel		S	Unknown	Unk	Amgen
	Actemra		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Ergocalciferol		C	Unknown	Unk	Not Reported
	Leucovorin		C		Unk	Not Reported
	Prednisone		C		Unk	Not Reported
	Apo-Hydroxyquine		C		Unk	Not Reported
	Calcium		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	12572852	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015113554		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Plaquenil	S	Oral	200 Milligram, Bid		Not Reported
Prednisone	S	Oral	5 Milligram, Qd		Not Reported
Sulfasalazine	S	Unknown	1000 Milligram, Bid		Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid		Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Qd		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 4 Times/Wk		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk		Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	13165940	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017014229		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S	Subcutaneous	50 Mg, Qmo		Amgen
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Vimovo			C		Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

	Esomeprazole Magnesium Trihydrate			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	13288085	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017030438		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	13380121	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017045167		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain;	Enbrel			S	Unknown	Unk		Amgen
	Cosopt			S	Unknown	Unk Unk, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Sciatica; Treatment Failure	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Qd	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk Unk, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Codeine Phosphate	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Levothyroxine	S	Unknown	Unk Unk, Qd	Not Reported
	Levothyroxine	S	Unknown	Unk	Not Reported
	Ramipril	S	Unknown	1 Dosage Form, Qd	Not Reported
	Ramipril	S	Unknown	Unk, Unk, Qd	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	Unk Unk, Qd	Not Reported
	Altace	S	Unknown	1 Dosage Form, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Levothyroxine Sodium	S	Unknown	Unk Unk, Qd	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Unk Unk, Bid (2 Every 1 Day)	Not Reported

Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Unk	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Unk	Not Reported
Caffeine	C		Unk	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Acetaminophen	C	Oral	1000 Milligram	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C	Unknown	Unk	Not Reported
Acetaminophen W/Codeine Phosphate	C		Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Meprobamate	C		Unk	Not Reported
Phosphate [Phosphoric Acid Sodium]	C		Unk	Not Reported
Timolol Maleate	C	Unknown	2 Dosage Form, Qd	Not Reported
Tylenol No.2	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	13436464	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016078528		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Tocilizumab	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	125 Milligram, Qwk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Gabapentin	C	Oral	400 Milligram, Tid 2 Tablets In The Mornings. 1 Tablet In The Aftenoon And 2 Tablets In The Evenings	Not Reported
	Gabapentin	C			Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Tylenol Arthritis	C	Unknown	650 Milligram, Qid	Not Reported
	Acetaminophen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	13667464	EXPEDITED (15-DAY)		OT	CA-ROCHE-1950692		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness;	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Months		Not Reported

Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 7 Months	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Therapy Duration: 2 Years	Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 10 Months	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Pantoprazole	C			Not Reported
	Atorvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	13909412	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017128000		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported

Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

Zopiclone	C	Unknown	7.5 Milligram, Qd		Not Reported
Zopiclone	C	Oral	Unk		Not Reported
Tenofovir	C		Unk		Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk		Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk		Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk		Not Reported
Pantoprazole Sodium	C	Unknown	Unk		Not Reported
Pantoprazole Bluefish	C	Unknown	Unk		Not Reported
Pantoprazole	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	14109381	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017157043			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Tiaprofenic	C		300 Mg, Qd		Not Reported
Plaquenil	C	Unknown	Unk		Not Reported
Aspirin	C		81 Mg, Qd		Not Reported
Aspirin	C	Unknown	Unk		Not Reported
Acetylsalicylic Acid	C		81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	14185061	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170005		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Rituximab			S	Unknown	1000 Milligram		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	14224287	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175535		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	14312157	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016084874		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Humira	S	Unknown	40 Milligram, Q2wk	Not Reported
Humira	S	Unknown	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Ciclosporin	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not	3 Milligram/Kilogram	Not Reported

		otherwise specified)		
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Orencia	S	Unknown	75 Milligram, Qmo	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C		5 Milligram, Qd	Not Reported
Cimzia	C	Subcutaneous	200 Milligram, Q2wk	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15206458	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018100976		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported

Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Humira		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira		S	Subcutaneous	40 Milligram, Unk	Not Reported
	Methotrexate		S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	20 Milliliter, Qwk	Not Reported
	Methotrexate		S	Intravenous (not otherwise specified)	20 Milliliter, Qwk	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15350864	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013388		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	7.5 Milligram		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Four Every One Week		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15556413	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016071038		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Enbrel		S	Unknown	Unk	Amgen
	Methotrexate Sodium		S	Unknown	25 Mg, Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Leflunomide		S	Oral	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Lyrica		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Mirtazapine		S	Unknown	15 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	25 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15692314	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018171978		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15710630	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181203762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Tylenol	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15732948	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594054-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Gold			C				Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15811039	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617171-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C	Oral			Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Tylenol Arthritis			C				Not Reported
	Tylenol			C				Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15855795	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634312-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Humira			S	Subcutaneous	Cyclical		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	For 3 Months		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported

Methotrexate Sodium	S	Subcutaneous	Not Reported
Plaquenil	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported

	Methotrexate	S	Intramuscular		Not Reported
	Rituximab	S	Intravenous drip	Cyclical	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	15951897	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019020117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16075459	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012877		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every		Aurobindo

Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer				Week	
	Actemra	S	Intravenous (not otherwise specified)	680 Milligram, 1 Every 4 Week	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	360 Milligram, 1 Every Month	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every Month	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Two Times A Day	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported

	Ciclosporin	S	Unknown	150 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16444293	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822475-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Cyclical		Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported

	Actonel	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	Cyclical	Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Cimziasingle	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Risedronate	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Risedronate Sodium	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16449347	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Gait Inability; Joint Swelling; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Tramadol Hydrochloride			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Leflunomide			C	Unknown	20 Milligram, Once A Day		Not Reported
	Methotrexate			C	Oral	15 Milligram, Every Week		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Every Week		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Milligram, Every Week		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16510049	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570129-00		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16532066	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2844164-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Arava			C				Not Reported

	Xeljanz	C	Not Reported
	Hydroxychloroquine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16807517	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Enbrel			S	Unknown	Unk		Amgen
	Bactrim			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16807532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	8 Milligram		Amgen
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported

Methotrexate	S	Unknown	20 Milligram, Qd		Not Reported
Orencia	S	Unknown	750 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram		Not Reported
Leflunomide	S	Unknown	20 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram		Not Reported
Gold	S	Unknown	50 Milligram		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16972574	EXPEDITED (15-DAY)		DE, OT	CA-ABBVIE-19K-028-2978585-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis;	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Terminal State	Doxycycline Hyclate	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Simponi	C	Unknown		Not Reported
	Rituximab W/Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	16980942	NON-EXPEDITED			US-SA-2019SA121847			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Exposure During Pregnancy; Urticaria	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi
	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17255133	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-40661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Off Label Use; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S				Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not	Unknown, Powder For		Not Reported

			otherwise specified)	Solution	
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown,Solution Subcutaneous	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Enbrel	C	Unknown	Unknown	Not Reported
	Azathioprine Sodium	C	Unknown	Unknown	Not Reported
	Cimzia	C	Subcutaneous	Unknown, Solution Single Use Pre-Filled Syringe	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17283605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005143		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk (Once In 4 Weeks)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q.M.T.		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Xeljanz	S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	Unk Unk, Q.Wk.	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Folic Acid	C	Unknown	5 Mg, Unk	Not Reported
	Naproxen	C	Unknown	500 Mg, Bid	Not Reported
	Naproxen	C	Unknown	500 Mg, (2 Every 1 Weeks)	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17553274	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2019148132		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Apo Prednison			S	Unknown	7 Milligram, Qd		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Milliliter, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Milligram, Qd		Not Reported

	Simponi	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Celecoxib	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17662149	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR061561		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Antinuclear Antibody Positive; Arthropathy; Asthenia; Blood Cholesterol Abnormal; Bronchitis; Butterfly Rash; Contusion; Depression; Dizziness; Emotional Disorder; Fatigue; Feeling Abnormal; Fibromyalgia; Headache; Hypertension; Malaise; Memory Impairment; Myalgia; Nasopharyngitis; Nausea; Nervousness; Neuralgia; Pneumonia; Post-Traumatic Stress Disorder; Product Use Issue; Rash Erythematous; Retinal Disorder; Sinus Disorder; Skin Discolouration; Skin Disorder; Skin Lesion;	Benlysta			S		Unk		Glaxosmithkline
	Noritate			S		Unk		Not Reported
	Ratio Clobetasol			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Social Problem; Stomatitis; Stress; Systemic Lupus Erythematosus; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17726348	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004004068			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Renal Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Cefepime Hydrochloride			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17739711	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004131			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use; Respiratory Distress; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17776135	EXPEDITED (15-DAY)		OT	CA-ROCHE-1671209		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Tolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Intentional Product Use Issue; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Vomiting	Actemra	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 4 Months	Not Reported
	Orencia	S	Subcutaneous	Therapy Duration: 9 Months	Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 9 Months	Not Reported
	Simponi	S	Unknown	Therapy Duration: 9 Months	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Celebrex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17986771	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020105852		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	50 Milligram, Qd		Not Reported
	Prednisone			S	Oral	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Milligram (Intravenous (Not Otherwise Specified)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram, Bid (Intravenous (Not Otherwise Specified)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Simponi			S	Unknown	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Leflunomide		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18067236	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019155881		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intramuscular	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd	Not Reported
	Naproxen	C	Unknown	500 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Bupropion	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18194820	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2020327634		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure; Sepsis	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil S			S	Oral	200 Mg, 2x/Day		Not Reported
	Prolia			C	Subcutaneous	60 Mg, Cyclic (Every 6 Months)		Not Reported
	Prednisone			C	Oral	5 Mg, As Needed		Not Reported
	Prednisone			C				Not Reported
	Senokot			C	Oral	8.6 Mg, 2x/Day		Not Reported
	Senokot			C				Not Reported
	Synthroid			C	Oral	50 Ug, Daily		Not Reported
	Spironolactone			C	Oral	25 Mg, Daily		Not Reported
	Systane Ultra			C	Ophthalmic	1 Drop Each Eye, 4x/Day		Not Reported
	Hydromorphone			C	Oral	3 Mg As Needed		Not Reported
	Apo Digoxin			C	Oral	0.062 Mg, Daily		Not Reported
	Warfarin			C	Oral	1 Mg As Needed		Not Reported
	Ramipril			C	Oral	2.5 Mg, Daily		Not Reported
	Apo Esomeprazole			C	Oral	20 Mg, Daily		Not Reported
	Furosemide			C	Oral	40 Mg, Daily		Not Reported

	Bisoprolol		C	Oral	2.5 Mg, Daily	Not Reported
	Atorvastatin		C	Oral	20 Mg, Daily	Not Reported
	Vitamin B12 [Vitamin B12 Nos]		C	Oral	1000 Mg, Daily	Not Reported
	Trazodone		C	Oral	50 Mg, Daily	Not Reported
	Trazodone		C			Not Reported
	Calcium		C	Oral	500 Mg, Daily	Not Reported
	Vitamin D3		C	Oral	1000 Iu, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18243527	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200841891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18246056	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010705		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cardiac Disorder; Cardiomyopathy; Feeling Abnormal; Loss Of Personal Independence In	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Daily Activities; Poor Quality Sleep; Product Complaint; Product Substitution Issue	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18246076	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035148		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride			S		Unk Milligram		Ucb
	Arava			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Golimumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk Milligram		Not Reported
	Methotrexate			S		20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Alendronate Sodium;Alendronic Acid			S		Unk		Not Reported
	Cortisone Acetate			S				Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S		Unk		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S		Unk Milligram	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Pseudoephedrine Hydrochloride	S		10 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S		Unk Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Diclofenac Potassium	C			Not Reported
	Diclofenac Sodium	C			Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Salazopyrin	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Apo-Prednisone	S		Unk	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Mg A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18246232	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035161		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		25 Milligram		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported

Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S			Not Reported
	Xeljanz	S		5 Milligram	Not Reported
	Xeljanz	S		Unk	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral	Unk	Not Reported
	Alendronate Sodium;Alendronic Acid	S			Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Gram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine	S		400 Milligram	Not Reported

Paracetamol	S			Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S	Oral	25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S			Not Reported
Leflunomide	C			Not Reported
Caffeine;Codeine;Paracetamol	C			Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Rituxan	S			Not Reported
Actemra	S		Unk	Not Reported
Alendronic Acid	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Salazopyrin	S		Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S		10 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S		Unk	Not Reported
Atasol [Paracetamol]	C			Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18246395	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020035129		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Chlorhexidine Gluconate			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased	Humira	S	Subcutaneous	40 Mg	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate [Methotrexate Sodium]	S	Oral	20 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Mg Solution For Infusion	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tofacitinib	S		10 Mg	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral	Unk	Not Reported
	Chlorhexidine Gluconate;Isopropanol	S			Not Reported
	Cortisone	S	Topical	25 Mg	Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S		Unk	Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Oxycodone;Paracetamol	S			Not Reported
	Phthalylsulfathiazole	S	Oral	500 Mg	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Mg	Not Reported
	Prednisone	S	Oral	7.5 Mg	Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Zopiclone	C			Not Reported
	Atasol [Paracetamol]	C			Not Reported
	Acetaminophen	S			Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Once Daily (Qd)	Not Reported
	Cetirizine Hydrochloride	C			Not Reported

Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		10 Milligram	Ucb
Pantoloc [Pantoprazole]	C			Not Reported
Fosamax	S	Oral		Not Reported
Pantoprazole Sodium	C			Not Reported
Tofacitinib Citrate	S		10 Milligram, Once Daily (Qd)	Not Reported
Paracetamol/Codeine	C			Not Reported
Tylenol [Paracetamol]	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Apo-Prednisone	S	Oral		Not Reported
Sulfathalidine	S	Oral	2000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S		500 Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	3011.2 Weekly	Not Reported
Actemra	S		752 Milligram	Not Reported
Actemra	S		728 Mg	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Oxycodone And Acetaminophen	S			Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Marvelon 28	C			Not Reported
Oxycodone Hcl Controlled Release	S			Not Reported
Chloraprep	S	Topical	Topical Solution	Not Reported
Sulfamethoxazole	S			Not Reported
Reactine [Cetirizine Hydrochloride]	C			Not Reported
Tylenol With Codeine	C			Not Reported
Oxycodone	S			Not Reported
Periogard	S	Buccal	Solution	Not Reported
Topicorte	S	Cutaneous		Not Reported
Desogestrel And Ethinylestradiol	C		Unk	Not Reported

	Ibuprofen	C			Not Reported
	Salazopyrin	C			Not Reported
	Cetirizine	S		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18246494	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Subcutaneous			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	4 Mg Cutaneous Solution		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Oral	25 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S				Not Reported
	Simponi			S	Subcutaneous	Pre Filled Syringe		Not Reported
	Stelara			S		Injection, Solution		Not Reported
	Xeljanz			S		5 Milligram, 2x/Day (Bid)		Not Reported
	Alendronate Sodium;Alendronic Acid			S	Oral			Not Reported
	Cortisone Acetate			S		25 Mg		Not Reported
	Desoximetasone			S	Oral			Not Reported

Desoximetasone	S	Subcutaneous		Not Reported
Diclofenac	S			Not Reported
Folic Acid	S		1 Mg	Not Reported
Folic Acid	S	Oral	25 Mg	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Prednisone	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Hydroxyquine	S			Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S			Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Infusion, Solution	Not Reported
Apo-Prednisone	S			Not Reported
Fosamax	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)	Infusion, Solution	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18247878	EXPEDITED (15-DAY)		DS	CA-UCBSA-2020035134		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister;	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Mg		Not Reported

Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate	S	Oral	200 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S		Unk	Not Reported
	Tofacitinib	S		5 Mg	Not Reported
	Xeljanz	S		5 Mg	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Diclofenac	S			Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg	Not Reported
	Paracetamol	S		Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	1000 Mg	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tofacitinib Citrate	S		5 Mg	Not Reported
	Reactine [Cetirizine Hydrochloride]	S		10 Mg	Not Reported

	Salazopyrin	C				Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S		Unk		Not Reported
	Golimumab	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18248562	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S				Not Reported
	Cosentyx			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate [Methotrexate Sodium]			S	Intracardiac			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alendronate Sodium;Alendronic Acid			S	Intracardiac			Not Reported
	Ascorbic Acid			S				Not Reported
	Calcium Glubionate			S				Not Reported
	Calcium Carbonate			S				Not Reported
	Calcium			S				Not Reported
	Colecalciferol			S				Not Reported
	Desoximetasone			S				Not Reported

	Diclofenac Sodium	S			Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Phthalylsulfathiazole	S	Intracardiac		Not Reported
	Prednisone	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Intracardiac		Not Reported
	Pantoprazole Sodium	C			Not Reported
	Calcium Gluconate	C			Not Reported
	Quetiapine [Quetiapine Fumarate]	C			Not Reported
	Ramipril	C			Not Reported
	Fosamax	S	Intracardiac		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Actemra	S	Intracardiac		Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18250479	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035247			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Ucb
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate [Methotrexate Sodium]			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Alendronate Sodium;Alendronic Acid	S			Not Reported
	Cortisone Acetate	S			Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Ucb
	Tocilizumab	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Apo-Prednisone	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18250604	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035267		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported

Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Alendronate Sodium	S			Not Reported
	Cortisone Acetate	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S		40 Milligram	Not Reported
	Prednisone	S		Unk	Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
	Tocilizumab	S			Not Reported
	Diclofenac	C			Not Reported
	Sulfasalazine	C			Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
	Actemra	S		Unk	Not Reported
	Rituxan	S			Not Reported
	Salazopyrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18251470	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020180866		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Cortison			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported

	Flumetasone Pivalate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	1000 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram	Not Reported
	Apo-Prednisone	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	9999	Not Reported
	Topicorten	S	Cutaneous	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Actemra	S	Subcutaneous	Pre Filled Syringe	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18251485	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020180847		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Cetirizine Hydrochloride			S	Unknown	10 Milligram, Once Daily (Qd)		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline

Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	500 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 2x/Day (Bid)	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

Leflunomide	S	Unknown	Unk		Not Reported
Topicort (Desoximetasone)	S	Cutaneous	Unk		Not Reported
Tocilizumab	S	Endocervical	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	S	Unknown	5 Milligram		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Paracetamol	C	Unknown	Unk		Glaxosmithkline
Codeine Phosphate	C	Unknown	Unk		Glaxosmithkline
Caffeine Citrate	C	Unknown	Unk		Not Reported
Atasol (Paracetamol)	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18253632	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035225			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis;	Cimzia			S	Subcutaneous			Not Reported
	Zyrtec-D			S		Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	4 Mg		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S				Not Reported

Systemic Lupus Erythematosus; Wound	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S			Not Reported
	Xeljanz	S		5 Milligram	Not Reported
	Alendronate	S	Oral		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S			Not Reported
	Desoximetasone	S			Not Reported
	Diclofenac	S			Not Reported
	Flumetasone Pivalate	S	Subcutaneous		Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S	Oral	25 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Tocilizumab	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Mg A Day	Not Reported
	Fosamax	S	Oral		Not Reported
	Reactine [Cetirizine Hydrochloride]	S		Unk	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Topicorten	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18253712	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Subcutaneous	500 Milligram		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18275235	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020150103			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18275726	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017797		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Poor Quality	Acetaminophen			S	Oral	Unk		Apotex
	Hydromorphone			S	Oral	12 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Oxycodone			S	Oral	Unk		Not Reported
	Oxycodone Terephthalate			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Sleep; Therapeutic Product Effect Incomplete; Vomiting	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18275771	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06072		74 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Loading Dose On Day 1)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (Maintainance Dose For The Next 4-9 Days)		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Favipiravir			C	Unknown	Unk		Not Reported
	Carvedilol			C	Unknown	6.25 Milligram, Qd		Not Reported
	Sevelamer			C	Unknown	2400 Milligram, Qd		Not Reported
	Low Molecular Weight Heparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18275819	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06073		61 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Loading Dose On Day 1)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (Maintenance Dose For The Next 4-9 Days)		Lupin

Favipiravir	C	Unknown	Unk		Not Reported
Aspirin [Acetylsalicylic Acid]	C	Unknown	100 Milligram, Qd		Not Reported
Sevelamer	C	Unknown	2400 Milligram, Qd		Not Reported
Carvedilol	C	Unknown	12.5 Milligram, Qd		Not Reported
Low Molecular Weight Heparin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18275874	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06074		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glucocorticoid Deficiency; Hypoglycaemia; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (Loading Dose On Day 1)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (Maintenance Dose For The Next 4-9 Days)		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	100 Milligram, Qd		Not Reported
	Amlodipine			C	Unknown	10 Milligram, Qd		Not Reported
	Low Molecular Weight Heparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18275971	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020150149		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthritis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling;	Enbrel			S	Subcutaneous	40 Mg, Weekly		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, 2x/Day		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Not Reported

Laboratory Test Abnormal; Mucosal Inflammation; Off Label Use; Pneumonia; Treatment Failure	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk, Qmo (8.0 Mg/Kg)	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Cortisone	C	Oral	5 Mg	Not Reported
	Prednisone	C		Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Oral	5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276181	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06025		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	400 Milligram, Qd (Days 2-5)		Lupin
	Tocilizumab			S	Unknown	800 Milligram, Single (9 Mg/Kg; Single Dose)		Not Reported
	Azithromycin			C	Oral	500 Milligram, Qd		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus			C	Unknown	1.5 Milligram, Bid (A Trough Goal Of 2-4 Ng/Ml)		Not Reported
	Ceftriaxone			C	Unknown	1 Gram, Qd		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276193	EXPEDITED (15-DAY)		OT	BE-LUPIN PHARMACEUTICALS INC.-2020-06006		55 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276249	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-048129		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Oral	10 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276267	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202009008632			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Heart Valve Incompetence; Musculoskeletal Stiffness; Pain; Pleural Effusion; Sensitivity To Weather Change	Hydroxychloroquine			S	Unknown	Plaquenil		Concordia
	Humira 40mg/0.8ml			S	Subcutaneous	40 Mg (40 Mg,1 In 2 Wk)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 2 Wk)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg		Not Reported
	Digoxin			C		Unk Ug		Not Reported
	Furosemide			C				Not Reported
	Metoprolol Succinate			C		100 Mg, 2 Tablet		Not Reported
	Chlorthalidone			C		25 Mg		Not Reported
	Atenolol			C		25 Mg		Not Reported
	Gabapentin			C		300 Mg		Not Reported
	Lovastatin			C		40 Mg		Not Reported
	Voltaren			C				Not Reported
	Metoprolol			C		100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276376	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1826935		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Nausea	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S				Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276499	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Methotrexate (Trade Name			S	Oral			Not Reported

Ineffective; Joint Swelling; Pain	Unknown)				
	Lyrica	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276567	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-06018		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Torsade De Pointes	Hydroxychloroquine			S	Oral	400 Milligram, Bid On Day 1		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid-For 4 Days		Lupin
	Azithromycin			S	Oral	500 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276638	EXPEDITED (15-DAY)		HO	CA-ROCHE-2678121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276676	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202009008668			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Exostosis; Gastrointestinal Disorder; Rheumatoid Nodule	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Methotrexate			S	Subcutaneous	20 Mg, Weekly		Not Reported
	Leflunomide			S	Unknown	10-20 Mg Once Daily		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276921	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3561455-00		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Failure; Off Label Use	Lopinavir/Ritonavir			S	Oral	400/100 Mg/12 H		Not Reported
	Methylprednisolone			S	Unknown	60 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q12 H		Not Reported
	Simvastatine			C	Oral	20 Mg		Not Reported
	Omeprazol			C	Oral	20 Mg		Not Reported

	Hidroferol	C	Unk Unk, Qm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276931	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020356007		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Vancomycin Hcl			S				Pfizer
	Piperacillin/Tazobactam			S		Unk		Pfizer
	Piperacillin/Tazobactam			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported
	Acetaminophen			S				Not Reported
	Oxygen			C		Unk (2-4 L)		Not Reported
	Oxygen			C		15 L (Requirement Acutely Worsened)		Not Reported
	Natalizumab			C		Unk (Infusion)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277243	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06075		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Enoxaparin Sodium			C	Subcutaneous	0.5 Milligram/Kilogram, Qd		Not Reported
	Enoxaparin Sodium			C	Unknown	Received Therapeutic Dose Of Enoxaparin Sodium		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Milligram		Not Reported

	Eculizumab	C	Intravenous (not otherwise specified)	900 Milligram	Not Reported
	Eculizumab	C	Intravenous (not otherwise specified)	1200 Milligram	Not Reported
	Heparin	C	Intravenous (not otherwise specified)	Received As Therapeutic Continuous Heparin	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277300	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020359229		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Weekly (1 Every 1 Weeks)		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly (1 Every 1 Weeks)		Pfizer
	Rituximab			S	Intravenous drip	1000 Mg		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Weekly (1 Every 1 Weeks)		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly (1 Every 1 Weeks)		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Meloxicam			C	Oral	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277451	EXPEDITED (15-DAY)		OT	CA-ACCORD-200615			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Orthostatic Hypotension; Palmoplantar Pustulosis; Presyncope; Rash; Red Blood Cell Sedimentation Rate Increased; Retinopathy	Methotrexate	S	Subcutaneous	Accord
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277719	EXPEDITED (15-DAY)		OT	CA-ACCORD-200844			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278153	EXPEDITED (15-DAY)		DE	CA-ASTRAZENECA-2020SF18373		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Omeprazole Magnesium			S	Oral	20.0mg Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown	10.0mg Unknown		Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium Bromide/Salbutamol			S	Unknown			Not Reported

Sulfate					
Lasix	S	Unknown	40.0mg Unknown		Not Reported
Metformin	S	Unknown			Not Reported
Nitrazadon	S	Unknown	10.0mg Unknown		Not Reported
Plaquenil	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Salmeterol Xinafoate	S	Unknown			Not Reported
Tylenol	S	Unknown	500.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278245	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1078448		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Nausea	Azithromycin			S		Unk		Mylan
	Ceftriaxona /00672201/			S		Unk		Mylan
	Kaletra			S		Unk		Mylan
	Hidroxicloroquina /00072601/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278794	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2020356104		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycin			S		500 Mg, Daily		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Favipiravir			S		Unk		Not Reported
	Ciclesonide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278831	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1079103		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Bid,Started On Hospital Day 6 As A Bridge To Compassionate Use Of Remdesivir; 2 Doses		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Mylan
	Tocilizumab			S	Unknown	800 Mg, Qd Given On Hospital Day 7 And 8		Mylan
	Remdesivir			S	Unknown	Off Label Use Of Remdesivir Started On Hospital Day 10; 100 Mg Daily For Five Doses		Mylan
	Vincristine			C	Unknown	Unk		Mylan
	Irinotecan			C	Unknown	Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278836	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1079095		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Herniation; Brain Oedema; Brain Stem Syndrome; Cerebral Haemorrhage; Coma; Off Label Use	Apixaban			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Enoxaparin			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278838	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1079096		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Herniation; Brain Midline Shift; Off Label Use; Subarachnoid Haemorrhage; Subdural Haematoma	Apixaban			S	Unknown	Unk		Mylan
	Heparin			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278840	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1079098		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Herniation; Brain Oedema; Cerebral Haemorrhage; Off Label Use; Subarachnoid Haemorrhage	Heparin			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278961	EXPEDITED (15-DAY)		OT	IT-SA-2020SA248227			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema; Hyperkeratosis; Lymphocytic Infiltration; Off Label Use; Rash Pruritic; Skin Degenerative Disorder; Skin Hyperpigmentation; Skin Lesion; Urticaria; Urticarial Vasculitis	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Ceftriaxone			S		Unk		Not Reported
	Enoxaparin Sodium			S		Unk		Sanofi
	Lopinavir/Ritonavir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278989	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28368			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

Prednisone	S	Unknown	Unknown		Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Levothyroxine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18279356	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18279474	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075821		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18280071	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020036605		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S				Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S		500 Milligram		Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)			
	Phthalylsulfathiazole	S				Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18280439	EXPEDITED (15-DAY)		DS, OT	CA-BECTON DICKINSON-2020BDN00210		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling;	Chlorhexidine			S	Topical	Unk		Becton Dickinson
	Chlorhexidine			S		Unk		Becton Dickinson
	Acetaminophen			S				Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	3011.2 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2912 Mg		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Cetirizine			S		10 Mg		Not Reported
	Chlorhexidine Gluconate Oral Rinse			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortison			S	Topical	25 Mg		Not Reported

Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S			Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Oxycodone-Acetaminophen	S			Not Reported
	Periogard Alcohol Free	S	Buccal		Not Reported
	Plaquenil	S	Oral	400 Mg	Not Reported
	Prednisone	S	Oral	7.5 Mg	Not Reported
	Pseudoephedrine	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfamethoxazole	S			Not Reported
	Sulfamethoxazole And Trimethoprim	S			Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Oral	2000 Mg	Not Reported

	Sulfathaladine	S	Oral	500 Mg	Not Reported
	Sulfathaladine	S	Oral	2000 Mg	Not Reported
	Sulfathaladine	S		Unk	Not Reported
	Topicort	S	Cutaneous		Not Reported
	Xeljanz	S		10 Mg	Not Reported
	Atasol	C			Not Reported
	Cetirizine	C			Not Reported
	Desogestrel/Ethinyl Estradiol	C			Not Reported
	Ibuprofen	C			Not Reported
	Pantoloc	C			Not Reported
	Pantoprazole	C			Not Reported
	Salazopyrin	C			Not Reported
	Tylenol	C			Not Reported
	Tylenol With Codeine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18280670	EXPEDITED (15-DAY)		OT	NVSC2020CA252975			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Topical	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Alendronic Acid			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sulfasalazine	S	Oral	1000 Mg		Not Reported
Sulfasalazine	S	Oral	2 G		Not Reported
Cimzia	S	Subcutaneous			Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk		Not Reported
Arava	S	Oral	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18312316	DIRECT					60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Intentional Product Use Issue; Petechiae; Thrombocytopenia	Lopinavir-Ritonavir			S	Oral	Other Dose:400/100mg;		Not Reported
	Ceftriaxone			S		Other Route:Iv		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Levofloxacin			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18312488	DIRECT		DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Diarrhoea Haemorrhagic	Lopinavir	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Prednisolone	S	Oral		Not Reported
	Ritonavir	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	11198503	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015012893		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram (3/C G2)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Leflunomide			C		20 Milligram, Qd		Not Reported

	Hydroxychloroquine Sulfate	C		200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Prednisone	C		5 Milligram, Qd	Not Reported
	Prednisone	C		10 Milligram, Bid	Not Reported
	Tocilizumab	C		Unk	Not Reported
	Gold	C			Not Reported
	Lyrica	C		75 Milligram, Qd	Not Reported
	Trazodone	C		50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	11475113	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015084414		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Eye Operation; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	12298212	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016050673		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alanine Aminotransferase	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen

Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	25 Milligram, Q2wk	Amgen
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Amgen
	Enbrel	S	Unknown	50 Milligram	Amgen
	Enbrel	S	Unknown	25 Milligram	Amgen
	Enbrel	S	Unknown	50 Milligram, Qwk	Amgen
	Etanercept	S	Unknown	25 Milligram, 2 Times/Wk	Amgen
	Etanercept	S	Unknown	50 Milligram, Qwk	Amgen
	Gold	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported

Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
Orencia	S	Unknown	780 Milligram, Qwk	Not Reported
Orencia	S	Unknown	760 Milligram, Qwk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram	Not Reported

Actemra	S	Unknown	360 Milligram, Qwk	Not Reported
Actemra	S	Unknown	360 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qwk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	17.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported

Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Q12h	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	70 Milligram, Qwk	Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	C	Oral	11 Milligram, Qd	Not Reported

Ciclosporin	C	Unknown	150 Milligram, Qd		Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h		Not Reported
Prednisone	C	Unknown	10 Milligram		Not Reported
Prednisone	C	Unknown	20 Milligram		Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Prednisolone	C		10 Milligram		Not Reported
Arava	C	Unknown	Unk		Not Reported
Arava	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	12321534	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054557		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qmo		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	12323846	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016053912		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Q2wk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	12336694	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2015094586		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Hypertension; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury;	Otezla			S	Oral	30 Milligram, Bid		Amgen
	Otezla			S	Oral	60 Milligram, Bid		Amgen
	Otezla			S				Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	20 Milligram, Qd		Amgen
	Etanercept			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Etanercept			S				Amgen
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Infliximab			S	Oral	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Subcutaneous	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Apremilast			S	Oral	30 Milligram, Bid		Not Reported
	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported

Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Pulmonary Fibrosis; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Ibuprofen	S	Oral	600 Milligram, Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Q4h	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Qd	Not Reported
	Ibuprofen	S	Oral	Unk Unk, Qd	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Unknown	6 Df, Qd	Not Reported
	Motrin	S	Oral	600 Milligram, Qd	Not Reported
	Motrin	S	Oral	Unk, Qd	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram 4 Every One	Not Reported

			Week	
Methotrexate	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
Methotrexate	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	70 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	2.5 Milligram, Qmo	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	7.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported

Cosentyx	S	Unknown	Unk	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituximab	S			Not Reported
Celebrex	S	Oral	200 Milligram, Bid	Not Reported
Benadryl	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	8 Milligram	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Form, Qwk	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Oxycodone	C		40 Milligram	Not Reported
Oxycodone	C		10 Milligram	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Uloric	C	Oral	8 Milligram, Bid; 160 Milligram, Bid	Not Reported
Oxyneo	C	Unknown	40 Milligram	Not Reported

Oxyneo	C	Unknown	10 Milligram		Not Reported
Dexilant	C	Oral	Unk		Not Reported
Gravol	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Naproxen	C		500 Milligram		Not Reported
Cannabis Sativa	C		Unk		Not Reported
Actonel	C	Oral	35 Milligram, Qwk		Not Reported
Vitamin D 3	C	Oral	2000 International Unit		Not Reported
Risedronate Sodium	C	Oral	35 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	12538837	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016070695		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Milligram, Bid		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported

Arava	S	Oral	200 Milligram, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Oral	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	Unk, Q2wk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
Hydroxychloroquine	C	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qwk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	Unk	Not Reported
Folic Acid	C	Oral	5 Milligram, Qd (6 Days Per Week)	Not Reported
Folic Acid	C	Oral	5 Milligram	Not Reported
Leflunomide	C	Oral	20 Milligram, Qd	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	12726405	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016247224		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bedridden; Crying; Drug Ineffective	Enbrel		S	Unknown	Unk	Pfizer
	Methotrexate Sodium		S	Unknown	Unk	Pfizer
	Actemra		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine		C		Unk	Not Reported
	Calcium		C		Unk	Not Reported
	Ergocalciferol		C	Unknown	Unk	Not Reported
	Leucovorin		C		Unk	Not Reported
	Prednisone		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	12945677	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016157990		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Erelzi [Etanercept]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Methotrexate	S	Subcutaneous	15 Milligram, Qwk		Not Reported
Methylprednisolone	S	Unknown	80 Milligram		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	400 Mg, Q8wk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Unk		Not Reported
Rituxan	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	13139174	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2011246063		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Pfizer
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported

Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Qmo	Not Reported
Arava	S	Oral	10 Milligram, Qd	Not Reported
Arava	S	Oral	10 Milligram, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Not Reported
Apo Hydroxyquine	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Asa Arthritis Strength Aspirin	C	Unknown	81 Milligram	Not Reported
Asa Arthritis Strength Aspirin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported

	Vitamin D	C		Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk, As Required	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Lozide	C	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk Unk, As Required	Not Reported
	Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Milligram	Not Reported
	Lantus	C	Unknown	Unk	Not Reported
	Lantus	C	Subcutaneous	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D3	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	13638421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017086096		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every 10 Days		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Humira	S	Unknown	40 Milligram	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	50 Milligram, Q4wk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Adalimumab	S	Unknown	40 Milligram, Q2wk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Tofacitinib	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported

Methotrexate	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Kevzara	S	Unknown	Unk		Not Reported
Kevzara	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown			Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd		Not Reported
Rabeprazole Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	13859207	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017119169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	13915127	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127978		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Anakinra			S	Unknown	100 Milligram, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk (Solution Subcutaneous)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	12.5 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	12.5 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Not Reported

Orencia	S	Unknown	500 Milligram, Q4wk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4mo		Not Reported
Orencia	S	Unknown	500 Milligram		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd		Not Reported
Xeljanz	C	Unknown	5 Milligram, 2 Times/Wk		Not Reported
Xeljanz	C	Unknown	Unk Unk, Bid		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	13932857	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017314		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Cyclosporine			S	Unknown	150 Mg, Qd		Apotex
	Methotrexate			S	Unknown	12 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	12 Mg, Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q.O.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported

Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Enbrel	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Q.O.Wk.	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk, 275 (Unspecified Unit)	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk, 365 (Unspecified Unit)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	360 Mg, Q.M.T.	Not Reported
	Actemra	S	Unknown	680 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	680 Mg, 1 Every 4 Week	Not Reported
	Actemra	S	Unknown	360 Mg, Q.Wk.	Not Reported

Myochrysine	S	Subcutaneous	50 Mg, Q.M.T.		Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.		Not Reported
Rituximab	S	Intravenous drip	1000 Mg, Bid		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
Fosamax	S	Unknown	70 Mg, Q.Wk.		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Ciclosporin	C	Unknown	150 Mg, Qd		Not Reported
Ciclosporin	C	Unknown	150 Milligram, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	14154998	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017164903		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unk		Not Reported
	Cephalexin	C		500 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	14190825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490362		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Unknown
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Pfizer
	Rituximab			S	Unknown	1000 Milligram		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	14235430	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2017AP021569		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis;	Hydroxychloroquine			S	Unknown	680 Milligram		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	360 Milligram, Q.M.T.		Apotex
	Apo-Leflunomide			S	Oral	500 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.I.W		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Apo-Ibuprofen			S	Oral	600 Milligram		Apotex
	Ibuprofen			S	Oral	600 Mg, Unk		Apotex
	Ibuprofen			S	Oral	600 Milligram, Qd		Apotex
	Ibuprofen			S	Oral	Unk, Qd		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Codeine			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	60 Mg, Bid		Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Oral	Unk		Not Reported
	Motrin			S	Oral	600 Mg, Qd		Not Reported
	Motrin			S	Oral	Unk Unk, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Intravenous (not	Unk		Not Reported

Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tongue Disorder; Ulcer			otherwise specified)		
	Stelara	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Two Every One Week	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	17.5 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	10 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.I.W	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Q.Wk.	Not Reported
	Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Q.12h	Not Reported

Rituximab	S	Intravenous drip	1000 Milligram, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	760 Milligram, Q.Wk.	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	I1000 Mg, Q.12h	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Intravenous (not otherwise specified)	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	360 Mg, One Every 4 Weeks	Not Reported
Actemra	S	Unknown	360 Mg, Q.Wk.	Not Reported
Actemra	S	Intravenous (not otherwise specified)	680 Milligram, Q.Wk.	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	360 Milligram	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.Wk.	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q.O.Wk.	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	360 Mg, One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Mg, One Every Four Week	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported

Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Humira	C	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	10 Mg, Unk	Not Reported
Methotrexate	C	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	12 Mg, Q.Wk.	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	C	Unknown	680 Mg, Unk	Not Reported
Tocilizumab	C	Unknown	360 Mg, Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	5 Mg, Unk	Not Reported
Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Alendronate	C	Unknown	Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Mg, Unk	Not Reported
Benadryl /00000402/	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported

Enbrel	C	Unknown	25 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Rituximab	C	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
Rituximab	C	Unknown	1000 Milligram, Bid		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	14612490	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018030916			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Pantoprazole			C	Unknown	Unk Unk, Tid		Not Reported
	Loperamide			C	Oral	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15567238	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015216227		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	1 Milliliter, Qwk (Injectable)		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly: 0.65 Ml, Weekly (Injectable), (Reduced To 0.65 Ml Since Start On Xeljanz		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Prednisone			S	Intravenous (not otherwise specified)	7 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Cellcept	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15580508	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017038118		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell	Enbrel			S	Subcutaneous	50 Mg, Qmo		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Sedimentation Rate Abnormal	Actemra		S	Subcutaneous	162 Mg, Every 2 Weeks	Not Reported
	Actemra		S	Subcutaneous	162 Mg, Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Esomeprazole Magnesium/Naproxen		C		Unk	Not Reported
	Folic Acid		C		Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	Unk	Not Reported
	Naproxen		C	Oral	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15623961	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557378-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous drip			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

Product Effect Incomplete; Treatment Failure; Unevaluable Event	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Cyclosporine	S	Oral	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Pregabalin	S	Oral	Not Reported
	Teva Mycophenolate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not	Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15686123	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573639-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Injection Bp		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported

Plaquenil	S	Unknown		Not Reported
Plaquenil	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Anakinra	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen	C	Unknown		Not Reported
Ativan	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Darifenacin	C			Not Reported
Desoximetasone	C	Oral		Not Reported
Desoximetasone	C	Intramuscular		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Diphenhydramine	C			Not Reported
Furosemide	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown	Sustained-Release	Not Reported
Kenalog	C	Intra-articular		Not Reported
Kenalog	C			Not Reported
Loperamide	C	Unknown		Not Reported

Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray,Metered Dose	Not Reported
Oxyneo	C	Unknown	Extended Release	Not Reported
Pantoprazole Sodium	C			Not Reported
Restasis	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown		Not Reported
Vagifem	C	Vaginal		Not Reported
Dexamethason	C	Intramuscular		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex	C	Unknown	(Extended Release)	Not Reported
Pantoprazole Sodium Anhydrous	C			Not Reported
Lasix	C			Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Dyclone	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Pantoloc	C	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported
Dexamethasone	C	Unknown		Not Reported
Orphenadrine Citrate	C			Not Reported
Loperamide Hydrochloride	C			Not Reported
Cortisone	C	Unknown		Not Reported
Cortisone	C	Unknown		Not Reported
Orphenadrine	C	Unknown		Not Reported
Orphenadrine	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15695394	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015052110		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk (For Four Months)		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram (3/C G2)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	20 Mg, Daily		Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Hydroxychloroquine Sulfate			C		200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Prednisone			C		5 Milligram, Qd		Not Reported

	Prednisone	C	10 Milligram, Bid	Not Reported
	Tocilizumab	C	Unk	Not Reported
	Gold	C	Unk	Not Reported
	Lyrica	C	75 Milligram, Qd	Not Reported
	Trazodone	C	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15700579	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018504596		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15708189	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2586143-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Zostavax		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Varicella Zoster Vaccine		S	Unknown	Liquid Intramuscular	Not Reported
	Etanercept		S	Subcutaneous		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15711487	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587408-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Actonel			C				Not Reported
	Amlodipine			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported

	Bisoprolol Fumarate	C	Not Reported
	Celebrex	C	Not Reported
	Ergocalciferol	C	Not Reported
	Folic Acid	C	Not Reported
	Metformin	C	Not Reported
	Pantoprazole	C	Not Reported
	Paroxetine	C	Not Reported
	Prednisone	C	Not Reported
	Risedronate	C	Not Reported
	Simvastatin	C	Not Reported
	Telmisartan	C	Not Reported
	Xeljanz	C	Not Reported
	Statex	C	Not Reported
	Mtx	C	Not Reported
	Morphine Sulphate	C	Not Reported
	Asa	C	Not Reported
	Risedronate Sodium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15920660	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1007761		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	15957210	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019066858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	16387275	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP015455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Ibuprofen			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Motrin [Ibuprofen]	S	Unknown	Unk		Not Reported
	Naprosyn [Naproxen Sodium]	S	Unknown	Unk		Not Reported
	Vitamin C [Ascorbic Acid]	S	Unknown	Unk		Not Reported
	Ascorbic Acid	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	16388032	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-030631		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Acetaminophenad			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	10 Milligram		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Oral	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram Once In A Week	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	25 Milligram	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	1 Gram, Two Times A Day	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	25 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Two Times A Day	Not Reported
Topicort	S	Cutaneous	Unk	Not Reported
Topicort	S	Oral	Unk	Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported
Topicort	S	Cutaneous	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	16443925	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033256		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated;	Alendronic Acid			S	Oral	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hcl			S	Unknown	Unk		Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hcl	S	Unknown	10 Milligram, Once A Day	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Cortisone Acetate	S	Oral	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Gram, Two Times A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S	Subcutaneous	1 Milligram, Two Times A Day		Not Reported
Sulfasalazine	S	Oral	1 Milligram, Two Times A Day		Not Reported
Cetirizine Hcl / Pseudoephedrine Hcl	S	Unknown	Unk		Not Reported
Pseudoephedrine	S	Unknown	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Topicorten	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	16625579	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2863484-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Viread	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	16817877	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Bactrim			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	16817883	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399548			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	8 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1x/Day		Pfizer

Label Use; Rheumatoid Arthritis; Vomiting	Actemra	S	Unknown	8 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	750 Mg	Not Reported
	Gold	S	Unknown	50 Milligram	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	16982974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2448420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17413693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546111			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

					otherwise specified)					
	Desoximetasone			C	Unknown					Not Reported
	Hydroxychloroquine Sulfate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17785416	EXPEDITED (15-DAY)		HO	MX-ADVANZ PHARMA-202004005048			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Off Label Use; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Dosage Form, Bid		Concordia
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lopinavir+ Ritonavir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17787717	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202004005019			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodynamic Instability; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid (Q12h)		Concordia
	Furosemide			C				Not Reported
	Clarithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Meropenem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17797376	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005211			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17815625	EXPEDITED (15-DAY)			MX-ADVANZ PHARMA-202005005423			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid(Q12h)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Ceftriaxone Sodium			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Oseltamivir Phosphate			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17850911	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202005005727			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Disorder	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Clarithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17852846	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005835			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Covid-19; Odynophagia; Off Label Use; Pyrexia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate			S				Concordia

(Authorized Generic),Plaquenil

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17852848	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005790			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Colic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17852855	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005836			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Covid-19; Myalgia; Off Label Use; Rhinorrhoea	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd (Hydroxychloroquine Sulfate Vs Placebo (Code Not Broken))		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17869608	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP011695		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter	Alendronate			S	Oral	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Diclofenac			S	Ophthalmic	Unk		Apotex
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex

Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Leflunomide	S	Oral	Unk	Apotex
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfathalidine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfathalidine	S	Oral	500 Mg, Unk	Not Reported
	Tofacitinib	S	Unknown	5 Mg, Bid	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
	Topicort /00370301/	S	Cutaneous	Unk	Not Reported
	Atasol /00020001/	C	Unknown	Unk	Not Reported

	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17898484	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202006006303			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypernatraemia; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Dosage Form, Bid (Q12h)		Concordia
	Propofol			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Clortalidone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17898490	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202006006292			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Dosage Form, Bid (Q12h)		Concordia
	Insulin			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17898495	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202006006305			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Off Label Use	Hydroxychloroquine			S		1 Dosage Form, Bid (Q12h) (200 Mg Every 12 Hours)		Concordia
	Midazolam			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Piperacillin + Tazobactam			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Vecuronium			C				Not Reported
	Enoxaparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Tobramycin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17902819	EXPEDITED (15-DAY)		DE, HO, OT	MX-ADVANZ PHARMA-202006006299			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Clarithromycin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17903600	EXPEDITED (15-DAY)		DE, HO, OT	MX-ADVANZ PHARMA-202006006320			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodynamic Instability; Off Label Use; Renal Impairment	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Insulin			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Vecuronium			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17929965	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202006006496			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Disorder	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Paracetamol			C				Not Reported
	Omeprazole			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Sulfamerazine;Trimethoprim			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17948663	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006006747			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Headache; Myalgia; Off Label Use; Productive Cough; Pyrexia; Rhinorrhoea; Sars-Cov-2 Test Positive	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17954660	EXPEDITED (15-DAY)		HO	MX-ADVANZ PHARMA-202006006684			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Acetylsalicylic Acid			C		Unk		Not Reported
	Atorvastatin Calcium			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17954661	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202006006675			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Off Label Use; Respiratory Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid, In Every 12 Hours		Concordia
	Clarithromycin			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported

Atorvastatin	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17960353	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202006006719			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal; Hypoventilation; Hypoxia; Off Label Use; Post Viral Fatigue Syndrome; Respiratory Disorder	Hydroxychloroquine			S	Oral	200 Mg, Bid (Q12h)		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17971607	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006006797			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Bid, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17972962	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202006006784			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Potassium Decreased; Blood Sodium Increased; Off Label Use; Respiratory Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Q12h (Every 12 Hours)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Clarithromycin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

Methylprednisolone	C	Unk	Not Reported
Paracetamol	C	Unk	Not Reported
Losartan	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17976768	EXPEDITED (15-DAY)		DE, HO, OT	MX-ADVANZ PHARMA-202006006800			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Aspartate Aminotransferase Increased; Electrocardiogram Qt Prolonged; Glomerular Filtration Rate Decreased; Lymphocyte Count Decreased; Off Label Use; Respiratory Rate Decreased; Sepsis; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17978298	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006006806			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Electrocardiogram Qt Prolonged; Glomerular Filtration Rate Decreased; Haemodynamic Instability; Off Label Use; Procedural Hypotension; Respiratory Failure	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	17994539	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202006006793			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bilirubin Conjugated Increased; Blood Bilirubin Increased; Covid-19; Drug Ineffective; Off Label Use; Respiratory Disorder	Hydroxychloroquine			S		200 Mg Every 12 Hours A Day		Concordia
	Chlortalidone			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Cephalosporin Nos			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18012008	EXPEDITED (15-DAY)		DE, HO, OT	MX-ADVANZ PHARMA-202006006995			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Potassium Decreased; Blood Triglycerides Increased; Condition Aggravated; Death; Electrocardiogram Qt Prolonged; Glomerular Filtration Rate Decreased; Haematuria; Hyperkalaemia;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg Every 12 Hour, Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

Hypertension; Lymphocyte Count Decreased; Off Label Use; Proteinuria; Respiratory Failure; Sepsis; Septic Shock

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18020814	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202006007083			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Blood Potassium Decreased; Blood Sodium Increased; Off Label Use; Superinfection Bacterial; Superinfection Fungal	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Dosage Form, Bid (Q12h)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Clarithromycin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Piperacillin, Tazobactam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18031689	EXPEDITED (15-DAY)		DE, HO, OT	MX-ADVANZ PHARMA-202007007142			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Potassium Decreased; Blood Sodium Increased; Off Label Use; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Q12h		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Clarithromycin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

	Carbapenem			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18037113	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202007007147			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Lymphocyte Count Decreased; Off Label Use; Transaminases Increased	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18041669	EXPEDITED (15-DAY)		DE, HO, OT	MX-ADVANZ PHARMA-202007007143			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Aspartate Aminotransferase Increased; Blood Sodium Increased; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Furosemlde			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Lopinavir + Ritonavir			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18062735	EXPEDITED (15-DAY)		DE, HO	MX-ADVANZ PHARMA-202007007280			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Sodium Increased; Off Label Use; Pyrexia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Dosage Form, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Norepinephrine			C				Not Reported
	Amiodarone			C				Not Reported

	Furosemide	C	Not Reported
	Enoxaparin	C	Not Reported
	Cephalosporin Nos	C	Not Reported
	Acetaminophen	C	Not Reported
	Insulin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18089389	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202007007432			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Sodium Increased; Cardiac Arrest; Off Label Use; Pyrexia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid (Q12h)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Meropenem			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Vecuronium			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18112152	EXPEDITED (15-DAY)		HO, OT	MX-ADVANZ PHARMA-202007007542			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Transaminases Increased	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18143760	EXPEDITED (15-DAY)		OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-256713		39 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Sun
	Prednisone			S	Unknown	10 Milligram, Qd		Mutual
	Mycophenolate Mofetil			S	Unknown	1 Gram, Bid		Not Reported
	Mycophenolate Mofetil			S	Unknown	0.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18166774	EXPEDITED (15-DAY)		HO	MX-ADVANZ PHARMA-202008008003			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Off Label Use; Transaminases Increased	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18192710	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202008008105			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Electrocardiogram Qt Prolonged; Off Label Use; Respiratory Distress; Transaminases Increased	Hydroxychloroquine			S	Oral	200 Mg, Bid (200 Mg, Q12h)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18239208	EXPEDITED (15-DAY)		LT, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-071021		48 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Electrocardiogram T Wave Inversion; Hepatic Enzyme Increased; Hyperbilirubinaemia; Intentional Product Use Issue; Jaundice; Lower Respiratory Tract Infection Bacterial; Pyrexia	Reyataz	S	Oral	400 Milligram, Qd	Bristol Myers Squibb
	Cefepime Dihydrochloride Monohydrate	S	Intravenous (not otherwise specified)	2 Gram At Drug Dose Interval Of 3units In Day	Bristol Myers Squibb
	Dafalgan	S	Oral	1,500-2,000 Mg Daily (500 Mg 1 To 4 Daily If Necessary)	Bristol Myers Squibb
	Dafalgan	S	Oral	1000 Milligram, Qd	Bristol Myers Squibb
	Tarivid [Ofloxacin]	S	Oral	Unk	Not Reported
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]	S	Oral	Unk	Not Reported
	Tazobac [Piperacillin Sodium;Tazobactam Sodium]	S	Intravenous (not otherwise specified)	4500mg At Drug Dose Interval Of 2 Day	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 Gram, Qd	Not Reported
	Supracyclin [Doxycycline Monohydrate]	S	Oral	200 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg Bid For Two Days On 23 And 24-Mar-2020, Then 200 Mg Bid	Not Reported
	Clexane	C	Subcutaneous	40 Milligram, Qd	Not Reported
	Midazolam	C	Unknown	Variable Doses As Of 24-Mar-2020 And Presumably Up To 06-Apr-2020	Not Reported
	Fentanyl	C	Unknown	Variable Doses As Of 24-Mar-2020 And Presumably Up To 06-Apr-2020	Not Reported
	Propofol	C	Unknown	Variable Doses As Of 24-Mar-2020 And Presumably Up To 06-Apr-2020	Not Reported
	Rocuronium	C	Unknown	Variable Doses As Of 24-Mar-2020 And Presumably Up To 06-Apr-2020	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18261762	EXPEDITED (15-DAY)		DE	IR-PFIZER INC-2020346896		63 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Nephropathy Toxic; Off Label Use	Hydrocortisone Sodium Succinate			S		100 Mg, 3x/Day (Every 8 Hours)		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Single		Not Reported
	Kaletra			S	Oral	400/100 Mg Twice Daily Orally		Not Reported
	Oseltamivir			S	Oral	75 Mg, Daily		Not Reported
	Cefepime			S	Intravenous (not otherwise specified)	500 Mg, 2x/Day		Not Reported
	Vancomycin			S		Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			C		500 Mg, 2x/Day		Not Reported
	Cellcept [Mycophenolate Mofetil]			C		500 Mg, 1x/Day		Not Reported
	Cyclosporine			C		75 Mg, 2x/Day		Not Reported
	Cyclosporine			C		50 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18263838	EXPEDITED (15-DAY)		OT	NVSC2020CA248604			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain;	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	500 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Qd		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Oral	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Topicort	S	Cutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown	5 Mg	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Actemra	S	Unknown		Not Reported
	Sulfasalazine	S	Subcutaneous	1 G	Not Reported
	Sulfasalazine	S	Subcutaneous	1 G, Bid	Not Reported
	Tocilizumab	S	Endocervical	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported

	Codeine Phosphate	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Caffeine Citrate	C	Unknown	Unk	Not Reported
	Atasol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18279204	EXPEDITED (15-DAY)		CA, OT	NVSC2020IT251831			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Microhaemorrhage; Congenital Cytomegalovirus Infection; Foetal Exposure During Pregnancy; Growth Retardation; Low Birth Weight Baby; Neonatal Hypoacusis; Premature Baby	Azathioprine			S	Transplacental	Maternal Dose: 50 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Maternal Dose: 100 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 200 Mg, Qod		Not Reported
	Magnesium Sulfate			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18279978	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027169			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Polyarthritis; Synovitis; Weight Decreased	Rituximab (Unknown)			S	Intravenous drip	750mg, 1 Every 1 Week		Not Reported
	Rituximab (Unknown)			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Depo-Medrol			C	Intra-articular	Suspension Intra-Articular		Not Reported
	Folic Acid			C				Not Reported

	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Prednisone	C	Oral		Not Reported
	Sulfamethoxazole And Trimethoprim	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Actemra	C	Unknown		Not Reported
	Bisoprolol	C			Not Reported
	Candesartan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18280073	EXPEDITED (15-DAY)		OT	CA-ROCHE-2675367		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Mellitus	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18280159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2673665		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18280222	EXPEDITED (15-DAY)		OT	CA-ROCHE-2675012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cortisone	S	Oral	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported

	Topicorte	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol With Codeine-Caffeine	C	Unknown	Not Reported
	Salazopyrina	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18280307	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06045		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Mesalamine			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Milligram, Qd		Not Reported
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Prednisone			C	Oral	25 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18280531	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06080		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Unfractionated Heparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18280641	EXPEDITED (15-DAY)		OT	PK-LUPIN PHARMACEUTICALS INC.-2020-06132		45 YR	Male	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Azithromycin	S	Oral	500 Milligram, Qd	Lupin
	Hydroxychloroquine	S	Unknown	400 Milligram Immediately At Hospitalisation	Lupin
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Lupin
	Meropenem	C	Intravenous (not otherwise specified)	500 Milligram, Tid	Not Reported
	Enoxaparin Sodium	C	Subcutaneous	40 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18280693	NON-EXPEDITED		HO	CA-AMGEN-CANSP2020150949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Gram, Bid		Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281234	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06012		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

	Lopinavir/Ritonavir	C	Unknown	Unk	Not Reported
	Immunoglobulins Nos	C	Unknown	0.4g/Kg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281527	EXPEDITED (15-DAY)		OT	NVSC2020GB253221			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dengue Fever	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281675	EXPEDITED (15-DAY)		DS, OT	CA-ALVOGEN-2020-ALVOGEN-114342		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Diclofenac Potassium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cambia			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Voltaren Sr			S	Oral			Not Reported
	Gold			C				Not Reported
	Cambia			S	Oral	1.0df Unknown		Not Reported
	Cambia			S	Oral			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Diclofenac	S	Oral	1.0df Unknown	Not Reported
	Diclofenac	S	Oral	75.0mg Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Voltaren Sr	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281735	EXPEDITED (15-DAY)		DE	CA-ASTRAZENECA-2020SF18362		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Losec			S	Oral	20.0mg Unknown		Not Reported
	Metformin			S	Unknown	1000.0mg Unknown		Not Reported
	Nitrazadon			S	Unknown	10.0mg Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown	500.0mg Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium Bromice/Salbutamol Sulfate			S	Unknown			Not Reported
	Lasix			S	Unknown	40.0mg Unknown		Not Reported
	Lipitor			S	Unknown	10.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281780	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA025867			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic	Rituximab (Unknown)			S	Intravenous (not	Unk		Not Reported

Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound			otherwise specified)		
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia Single-Use Pre Filled Syringe	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	1 Every 1 Days	Not Reported
	Leflunomide	S	Unknown		Not Reported

Methotrexate	S	Oral	25 Milligram, 1 Every 1 Days		Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Oral	1 Gram		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Prednisone	S				Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Pseudoephedrine Hcl	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Days		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Winpred	S	Oral			Not Reported
Etanercept	S	Unknown			Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous			Not Reported
Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281946	EXPEDITED (15-DAY)		OT	CA-ACCORD-201168		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; C-Reactive	Methotrexate			S	Unknown			Not Reported

Protein Increased; Drug Ineffective; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Joint Swelling; Malaise; Musculoskeletal Stiffness; Nausea; Pain; Spinal X-Ray Abnormal; Stress; Swelling; Tender Joint Count; Therapeutic Response Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282110	EXPEDITED (15-DAY)		OT	CA-ACCORD-201175		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Methotrexate			S		Frequency: 1 Every 24 Hours		Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Metaraminol			S				Not Reported
	Enbrel			S				Not Reported
	Aurothioglucose			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			C				Not Reported
	Simponi			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			S		Frequency: 1 Every 24		Not Reported

				Hours	
	Methotrexate	S	Endocervical	Frequency: 1 Every 24 Hours	Not Reported
	Hydroxychloroquine	S	Oral	Hydroxychloroquine Sulfate	Not Reported
	Hydroxychloroquine	S		Hydroxychloroquine Sulfate	Not Reported
	Hydroxychloroquine	S		Hydroxychloroquine Sulfate	Not Reported
	Leflunomide	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282598	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SF17899			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Disorder; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Esomeprazole Magnesium Trihydrate			S	Oral			Astrazeneca
	Folic Acid			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Golden Seal			C				Not Reported
	Remicade			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282674	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA252128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium	S	Unknown	Unk	Novartis
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Folic Acid	S	Unknown	500 Mg	Not Reported
	Folic Acid	S	Oral	25 Mg	Not Reported
	Folic Acid	S	Oral	5 Mg	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Df	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Alendronate Sodium Trihydrate	S	Oral	Unk Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	4 Mg	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydrocortisone Sodium Succinate	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Phthalylsulfathiazole	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282880	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020359292		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Movement Disorder; Pain; Tuberculosis	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Ibuprofen			S	Unknown			Pfizer
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Voltaren [Diclofenac]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282899	EXPEDITED (15-DAY)		OT	CA-SA-2020SA250493			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aphthous Ulcer; Back Pain; Constipation; Depression; Dysgeusia; Facial Pain; Fibromyalgia; Inflammation; Liver Function Test Increased; Malaise; Migraine; Neuropathy Peripheral; Osteoarthritis; Paraesthesia; Photosensitivity Reaction; Polyarthritis; Road Traffic Accident; Systemic Lupus Erythematosus; Therapeutic Response Decreased	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Ferrous Fumarate			S		300 Mg, Qd		Not Reported
	Leflunomide			S		Unk Mg		Sanofi
	Leflunomide			S		10 Mg, Qod		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Folic Acid			C		5 Mg, Qd, 5/7 Days A Week		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Tiazac [Diltiazem Hydrochloride]			C				Not Reported
	D			C		3000 Iu, Qd		Not Reported
	Maxalt			C				Not Reported
	Prednisone			C		5 Mg, Qd <5 Tabs Every 30 Days		Not Reported
	Salazopyrin			C		2 G, Qd		Not Reported
	Tramacet			C		2 Df, Bid		Not Reported
	Vit D			C		3000 Iu, Qd		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid;Tocopherol]			C				Not Reported
	Amitriptyline			S		10 Mg		Not Reported
	Amitriptyline			S		20 Unk		Not Reported
	Tramadol			S				Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			C		Unk Mg		Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			C		20 Mg		Not Reported
	Arthrotec			C				Not Reported
	Oxycocet			C		Unk Unk, Prn		Not Reported
	Fiorinal [Acetylsalicylic			C				Not Reported

	Acid;Butalbital;Caffeine]				
	Temazepam	C	15 Mg, Hs		Not Reported
	Topamax	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18283000	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017749			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Acetaminophen			S	Unknown			Apotex
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Propofol			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18283367	EXPEDITED (15-DAY)		DS, OT	CA-ALVOGEN-2020-ALVOGEN-114335		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Tecta			S	Oral			Not Reported
	Voltaren Sr			S	Oral			Not Reported

Xeljanz	S	Oral			Not Reported
Diclofenac Potassium	S	Oral	75.0mg As Required		Not Reported
Folic Acid	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Depo-Medrol	C	Intramuscular			Not Reported
Gold	C	Unknown			Not Reported
Pantoprazole	S	Oral	Pantoprazole Magnesium		Not Reported
Pantoprazole	S	Oral	Pantoprazole Magnesium		Not Reported
Lisinopril	S	Oral			Not Reported
Lisinopril	S	Oral	Lisinopril Dihydrate		Not Reported
Lisinopril	S	Oral	Lisinopril Dihydrate		Not Reported
Lisinopril	S	Oral	Apo-Lisinopril		Not Reported
Lisinopril	S	Oral	Apo-Lisinopril		Not Reported
Diclofenac	S	Oral	Apo-Diclofenac		Not Reported
Folic Acid	S	Unknown			Not Reported
Pantoprazole	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18283454	EXPEDITED (15-DAY)		OT	CA-ALVOGEN-2020-ALVOGEN-114339		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril			S	Oral			Not Reported
	Voltaren Sr			S	Oral	75.0mg As Required		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Synthroid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Tecta			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Methylprednisolone Acetate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18283499	EXPEDITED (15-DAY)		OT	CN-BAXTER-2020BAX018984		22 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Uric Acid Increased	Endoxan			S	Intravenous drip			Baxter
	Endoxan			S	Intravenous drip	Dose Re-Introduced		Baxter
	Fenle (Hydroxychloroquine Sulfate)			S	Oral	Dosage Form: Tablet		Not Reported
	Prednisone			S	Oral	Dosage Form: Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18283622	EXPEDITED (15-DAY)		OT	NVSC2020CA252089			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Topical	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Alendronic Acid			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg		Not Reported

	Sulfasalazine	S	Oral	2 G		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk		Not Reported
	Arava	S	Oral	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Subcutaneous	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18283952	EXPEDITED (15-DAY)		HO	NVSC2020DK250574		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Meningoencephalitis; Keratitis	Methotrexat "Ebewe" 2.5mg Tablets			S	Oral	20 Mg, Qw		Novartis
	Cimzia			S	Subcutaneous	200 Mg, Biw		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18284460	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA252357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain;	Diclofenac			S	Unknown	Unk		Novartis

Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Paracetamol	S	Unknown	10 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Alendronate Sodium Trihydrate	S	Oral	Unk	Not Reported
	Alendronate Sodium Trihydrate	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Mg	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram	Not Reported
	Cetirizine Hydrochloride And	C	Unknown	10 Mg	Not Reported

Pseudoephedrine					
Ascorbic Acid	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Glucosamine	C	Unknown	Unk		Not Reported
Lansoprazole	C	Unknown	Unk		Not Reported
Lorazepam	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Salmon Oil	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18284461	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA252345			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis;	Diclofenac			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported

Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tofacitinib	S	Unknown	10 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Mg	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18285209	NON-EXPEDITED			US-PFIZER INC-2020360053			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18285290	EXPEDITED (15-DAY)		DE	CA-ASTRAZENECA-2020SF18547		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Losec			S	Oral	20.0mg Unknown		Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown	10.0mg Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown	500.0mg Unknown		Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown	40.0mg Unknown		Not Reported
	Lipitor			S	Unknown	10.0mg Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ipratropium Bromide/Salbutamolsulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18285360	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1828572		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease; Surgery	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18285606	EXPEDITED (15-DAY)		OT	NVSC2020FR252730		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Oral	10 Mg, Qd		Novartis

	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18285687	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA252179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg		Not Reported
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Hydrocortisone Acetate			S	Cutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortison Acetate			S	Topical	25 Mg		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortison			S	Oral	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sarilumab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Unknown	5 Mg		Not Reported
Hydroxychloroquine	S	Oral	400 Mg		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Sulfasalazine	S	Oral	1000 Mg		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg		Not Reported
Codeine Phosphate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18318055	DIRECT		DE			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	11619820	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1477576-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Foot	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Dosage Forms		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Deformity; Foot Deformity; Hand Deformity; Hand Deformity; Hypertension; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Disorder; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)	Cyclical Frequency	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Actonel	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Risedronate Sodium	S	Oral		Not Reported
	Rituximab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	12507876	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016083007		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Enbrel	S	Subcutaneous	Unk	Amgen
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Kineret	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	100 Milligram, Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	30 Milligram, Qd	Not Reported
	Cortisone	C		Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Methotrexate Sodium	C	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	15629234	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558776-00		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pneumonia; Rash; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Dose Decreased		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Intravenous Drip		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported

	Doxycycline Hyclate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Colchicine	S	Oral	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported
	Codeine Phosphate	C		Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Codeine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	15629783	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557408-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	15717406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587385-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

Failure			otherwise specified)	
	Rituxan	S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Mobicox	C		Not Reported
	Remicade	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	16341215	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019078780		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk (Tablet)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			C		Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	16573391	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852936-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Simponi		C	Subcutaneous		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Prednisone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	16837551	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2861363-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfadiazine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Route Of Administration: Intravenous (Not Otherwise Specified)		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Naproxen	S	Oral		Not Reported
Baclofen	S	Unknown		Not Reported
Baclofen	S			Not Reported
Prednisone	C	Unknown		Not Reported
Vitamin D	C	Unknown		Not Reported
Tylenol	C			Not Reported
Hydromorphone	C	Oral		Not Reported
Folic Acid	C			Not Reported
Calcium Carbonate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	17358981	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020015573		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Simponi	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Desoximetasone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	17687062	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP013397		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Asthenia; Blood Cholesterol Increased; Bone Density Abnormal; Condition Aggravated; Contraindicated Product Administered; Disability; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Infusion Related Reaction; Intentional Product Use Issue; Joint Stiffness; Joint	Apo-Prednisone			S	Oral	50 Mg, Qd		Apotex
	Apo-Prednisone			S	Oral	25 Mg, Qd		Apotex
	Apo-Prednisone			S	Oral	3 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Cetirizine			S	Unknown	25 Milligram		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Diclofenac			S	Unknown	50 Mg, Unk		Apotex
	Leflunomide			S	Oral	200 Mg, Qd		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Apo Folic Acid			S	Unknown	Unk		Not Reported
	Apo Folic Acid			S				Not Reported
	Winpred			S	Oral	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk, Q.Wk.		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	0.5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported

Swelling; Knee Arthroplasty; Limb Deformity; Live Birth; Maternal Exposure During Pregnancy; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Folic Acid	S	Oral	25 Mg, Unk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Prednisone	S	Unknown	40 Milligram	Not Reported
	Prednisone	S			Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Cimzia	S	Subcutaneous	400 Mg, Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	20 Milligram, Q.Wk.	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4omg/0.8ml	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	4 Mg, Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd	Not Reported

Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	Unk Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	Unk Milligram	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S			Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported

Topicort Lp	S	Subcutaneous	Unk	Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S			Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Qd	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Salazopyrine	S	Unknown	Unk	Not Reported
Indocid /00003801/	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	Unk	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported
Cymbalta	C	Oral	30 Mg, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	17920113	EXPEDITED (15-DAY)		OT	CA-ACCORD-185840			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Certolizumab	S	Subcutaneous	Not Reported
	Cetirizine/Pseudoephedrine	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Calcium Gluconate	C	Unknown	Not Reported
	Quetiapine/Quetiapine Fumarate	C	Unknown	Not Reported
	Ramipril	C		Not Reported
	Pantoprazole	C		Not Reported
	Etanercept	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18119789	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1810156		65 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Treatment; Hepatocellular Injury	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Plaquinol			S	Oral	400mg 12 / 12h In D0 And Then 200mg 12 / 12h		Not Reported
	Enoxaparin Sodium			C	Subcutaneous			Not Reported
	Enoxaparin Sodium			C	Subcutaneous	20 Mg		Not Reported
	Quetiapine			C	Oral			Not Reported
	Esomeprazole			C	Oral			Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	4 Inhalations 6 / 6h		Not Reported
	Trazodone			C	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Piperacillin, Tazobactam			C	Intravenous (not otherwise specified)			Not Reported
	Clonidine			C	Oral			Not Reported
	Salbutamol			C	Respiratory (inhalation)	6 Inhalations 4 / 4h		Not Reported
	Escitalopram			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18174129	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-039984		83 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Amiodarone 200mg Tablets			S	Oral	200 Milligram, Once A Day		Aurobindo
	Kaletra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Aliflus	C	Respiratory (inhalation)	Unk	Not Reported
	Lobivon	C	Oral	2.5 Milligram, Once A Day	Not Reported
	Pantorc	C	Oral	20 Milligram, Once A Day	Not Reported
	Piperacillina/Tazobactam	C	Unknown	4500 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18279710	EXPEDITED (15-DAY)		OT	NVSC2020CA249045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Novartis
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cortisone Acetate			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Oral	25 Mg	Not Reported
Sulfasalazine	S	Oral	1 G	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Enbrel	S	Subcutaneous	20 Mg	Not Reported
Arava	S	Oral	20 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	400 Mg, Qd	Not Reported
Fosamax	S	Oral		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Actemra	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Caffeine	C	Unknown		Not Reported
Codeine Phosphate	C	Unknown		Not Reported

	Paracetamol		C	Unknown	Not Reported
	Salazopyrina		C	Unknown	Not Reported
	Atasol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18285671	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3569004-00		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Methotrexate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18285709	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2784928-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Migraine; Nausea; Off Label Use;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Cimzia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18285710	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-20K-163-3520112-00		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Macular Degeneration	Humira 40mg/0.4ml			S	Subcutaneous	Citrate Free		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	Citrate Free		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Proair			C				Not Reported
	Allopurinol			C				Not Reported
	Baby Aspirin			C				Not Reported
	Atenolol			C				Not Reported
	Atrovent			C				Not Reported
	Azelastine			C				Not Reported
	Tums			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin A			C				Not Reported
	Leflunomide			C				Not Reported

Levothyroxine	C		Not Reported
Singulair	C		Not Reported
Protonix	C		Not Reported
Pravachol	C		Not Reported
Vitamin D3	C		Not Reported
Vitamin C	C		Not Reported
Estradiol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18285756	EXPEDITED (15-DAY)		OT	CA-ACCORD-201177		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported
	Folinic Acid			C				Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18285840	NON-EXPEDITED			US-SA-2020SA250699			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation	Leflunomide			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Atenolol			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Sanofi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18285871	EXPEDITED (15-DAY)		OT	CA-ACCORD-201176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Accord
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18285872	EXPEDITED (15-DAY)		OT	CA-ACCORD-201169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Physical Health Deterioration; Mobility Decreased; Musculoskeletal Pain; Nervousness; Pain; Pain In Extremity	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Diclofenac			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18286187	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA253955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Diclofenac			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported

Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tofacitinib	S	Unknown	5 Milligram	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	1000 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported

	Caffeine Citrate	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18286188	EXPEDITED (15-DAY)		OT	NVSC2020CA254079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported

Cimzia	S	Subcutaneous	Unk		Not Reported
Arava	S	Oral	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Tofacitinib	S	Unknown	5 Mg		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	1000 Mg		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg		Not Reported
Phthalylsulfathiazole	S	Unknown	1000 Mg		Not Reported
Phthalylsulfathiazole	S	Oral	500 Mg		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg		Not Reported
Paracetamol And Codeine Phosphate (I)	C	Unknown	Unk		Not Reported
Caffeine Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18286207	EXPEDITED (15-DAY)		OT	NVSC2020CA252102			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy;	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk Mg		Novartis
	Paracetamol			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Unknown	25 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Folic Acid	S	Unknown	15 Mg	Not Reported
	Folic Acid	S	Unknown	500 Mg	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Alendronic Acid	S	Oral	Unk	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Prednisone	S	Unknown	1 Mg	Not Reported
	Prednisone	S	Unknown	5 Mg	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported

Xeljanz	S	Unknown	10 Mg		Not Reported
Hydroxychloroquine Phosphate	S	Oral	400 Mg		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Paracetamol Codeine	C	Unknown	Unk Mg		Not Reported
Caffeine Citrate	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	12583397	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015363640		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Off Label Use; Pain; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, 1x/Day		Pfizer
	Sulfasalazine			S		1000 Milligram, Bid		Pfizer
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported

Hydroxychloroquine	S	Oral	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	13216598	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Cortisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intra-arterial	Injection Im Iv Iar Int Ivr 25mg/Ml; Solution Intra Arterial		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration- 11.0 Month(S)		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported

Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 365.0	Not Reported
Fosamax	S	Oral		Not Reported
Reactine (Canada)	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Xeljanz	C			Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	15416078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	Not Reported
Celecoxib	C	Unknown	Not Reported
Hydromorphone Hcl	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	15636315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2215715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Folic Acid			S	Unknown	Unknown		Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown	Unknown		Not Reported
Prednisone	S	Unknown	Unknown		Not Reported
Reactine (Canada)	S	Unknown	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	16639862	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2867392-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz Xr			C				Not Reported
	Xeljanz			C				Not Reported
	Infliximab			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Tofacitinib Citrate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	17433139	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016091942		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Anxiety; Arthropathy; C-Reactive Protein; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Pain; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Enbrel	S	Unknown	Unk	Amgen
	Enbrel	S	Subcutaneous	Unk	Amgen
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported

Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S			Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Methotrexate	S	Unknown	25 Milligram (1 Every 24 Hours)	Not Reported
Methotrexate	S			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

	Vitamin C	C	Unk		Not Reported
	Vitamin D	C	Unk		Not Reported
	Glucosamine	C	Unk		Not Reported
	Lansoprazole	C	30 Mg, Bid		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18219138	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1821439		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Myasthenia Gravis Crisis; Off Label Use	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Immunoglobulin (Immunoglobulin G Human)			S	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulin (Immunoglobulin G Human)			S	Intravenous (not otherwise specified)	He Received Immune-Globulin Daily For 5 Days		Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18238021	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1824698		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown			Teva
	Propofol			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18286298	EXPEDITED (15-DAY)		OT	IL-LUPIN PHARMACEUTICALS INC.-2020-06071		34 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18286302	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06078		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Apixaban			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18286303	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06079		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Apixaban			C	Unknown	Unk		Not Reported
	Unfractionated Heparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18286306	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06097		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Bid (Two Doses)		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Lupin
	Vincristine			C	Unknown	Unk		Not Reported
	Irinotecan			C	Unknown	Unk		Not Reported
	Remdesivir			C	Unknown	100 Milligram, Qd (100 Mg Daily For Five Doses)		Not Reported
	Tocilizumab			C	Unknown	800 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18286307	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06104		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Single		Lupin
	Remdesivir			C	Unknown	200 Milligram, Qd (1 Dose (Compassionate Use))		Not Reported
	Remdesivir			C	Unknown	100 Milligram, Qd (9 Doses)		Not Reported
	Cytarabine			C	Unknown	Unk		Not Reported
	Hydroxyurea			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2020	18286329	EXPEDITED (15-DAY)		HO, OT	IL-LUPIN PHARMACEUTICALS INC.-2020-06116		38 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis; Off Label Use	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Tid (Three Times A Day)		Lupin
	Lopinavir/Ritonavir			S	Unknown	Unk Unk, Bid, 400/ 100 Mg		Not Reported
	Prednisone			S	Unknown	25 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Unk, Dose Increased		Not Reported
	Immune Globulin			C	Intravenous (not otherwise specified)	Unk Initial Dose Unknown		Not Reported
	Pyridostigmine			C	Unknown	60 Milligram (Five Times Per Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	11126079	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-023023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Inflammation; Interstitial Lung Disease; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Pneumonia; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram,Every 10 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	17 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	2 Milligram		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Subcutaneous	500 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	400 Milligram		Not Reported
	Naproxen			S	Unknown	500 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

Rabeprazole Sodium	C	Unknown	20 Milligram, Qd	Not Reported
Allopurinol	C	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown	Unk	Not Reported
Bisoprolol	C	Unknown	Unk	Not Reported
Digoxin	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Nifedipine	C	Unknown	Unk	Not Reported
Palafer	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Toloxin [Digoxin]	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Zinc Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	11274915	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015069595		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired	Enbrel			S	Subcutaneous	2.5 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	2.5 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Imuran			S	Unknown	Unk		Not Reported

Gastric Emptying; Influenza; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Surgery; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Arava	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Intramuscular	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	25 Milligram	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	11368759	NON-EXPEDITED		DE, HO, LT, OT	CA-AMGEN-CANSP2014104837		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S				Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Sodium Aurothiomalate			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk (Single Use Vial)	Not Reported
Ilaris	S			Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Kineret	C		Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
Prednisone	C		Unk Unk, Qd	Not Reported
Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	11382867	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2015267393		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	5 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Arava	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	11457175	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2015088317		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk (Intravenous Drip)	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Arava	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	11999787	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1618751		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Increased; Blood Pressure Increased; Cough; Drug Hypersensitivity; Fatigue; Fatigue; Immune System Disorder; Infusion Related Reaction; Nasopharyngitis; Oxygen Saturation Decreased; Oxygen Saturation Decreased; Pneumonia; Pneumonia Fungal; Pyrexia; White Blood Cell Count Decreased	Rituxan	S	Intravenous (not otherwise specified)	Previous Rituxan Infusion: 25/Feb/2020	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Diphenhydramine Hcl	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Pregabalin	C			Not Reported
	Rosuvastatin	C			Not Reported
	Aas	C			Not Reported
	Coversyl	C			Not Reported
	Dexilant	C			Not Reported
	Folic Acid	C			Not Reported
	Prednisone	C			Not Reported
	Actonel	C			Not Reported
	Methotrexate	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Docusate	C			Not Reported
	Hydromorphone	C			Not Reported
	Calcium	C			Not Reported
	Clonazepam	C			Not Reported
	Aspirin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12247551	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016042951		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	20 Milligram 1 Every 04 Hours		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Spinal Operation; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Apo-Prednisone	S	Unknown	20 Milligram, Qd	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Warfarin	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Warfarin Sodium	S	Unknown	Unk	Not Reported
	Warfarin Sodium	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk (Intravenous Drip)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk (Capsule And Tablet)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12302274	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016221150		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Alopecia;	Enbrel			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer

Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Pfizer
	Enbrel	S	Unknown	25 Mg, 2x/Week	Pfizer
	Enbrel	S	Unknown	50 Milligram	Pfizer
	Enbrel	S	Unknown	25 Mg, Unk (1 Every 2 Week)	Pfizer
	Enbrel	S	Unknown	50 Mg, Weekly	Pfizer
	Etanercept	S	Unknown	25 Mg, 2x/Week	Pfizer
	Etanercept	S	Unknown	50 Mg, Weekly	Pfizer
	Celebrex	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer

Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	Unk	Pfizer
Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Pfizer
Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Pfizer
Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Pfizer
Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Infliximab Hospira	S	Intravenous (not otherwise specified)	Unk	Pfizer
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not	1000 Milligram, Q12h	Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Unknown	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported

Humira	S	Unknown	40 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Milligram, Qwk	Not Reported
Actemra	S	Unknown	360 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qwk	Not Reported

Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Gold	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Prednisone	C	Unknown	10 Mg	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported

Cyclosporin	C	Unknown	150 Mg, 1x/Day		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, 2x/Day		Not Reported
Xeljanz	C	Oral	11 Milligram, Qd		Not Reported
Prednisolone	C		Unk		Not Reported
Leflunomide	C	Oral	20 Milligram		Not Reported
Leflunomide	C	Unknown	20 Milligram		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Arava	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12320466	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054551			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	772 Milligram, Qmo		Not Reported
	Apo Hydroxychloroquine			S	Oral	400 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram (1 Every 9 Months)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported

Methotrexate	S	Oral	25 Milligram, Qwk		Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk		Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qwk		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12338904	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016241427		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Rash; Skin Mass; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Mg, Once A Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Monthly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram S		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid (2 Every 1 Day)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, Bid		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd (1 Every 24 Hours)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Once Every Two Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Subcutaneous	50 Mg, Weekly (1 Every 1		Not Reported

				Week(S))	
	Apo-Hydroxyquine	S	Oral	400 Mg, Qd (1 Every 24 Hours)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd (1 Every 24 Hour)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12355072	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2015306460		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein	Etanercept			S	Subcutaneous	Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Pfizer
	Enbrel			S		25 Milligram		Pfizer
	Enbrel			S		Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	20 Milligram, Qd		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypertension; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Pulmonary Fibrosis; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Sulfasalazine	S	Oral	1 Gram, Bid	Pfizer
	Infliximab Hospira	S	Intravenous (not otherwise specified)	400 Milligram	Pfizer
	Infliximab Hospira	S	Intravenous (not otherwise specified)	300 Milligram	Pfizer
	Infliximab Hospira	S	Oral	Unk	Pfizer
	Ibuprofen	S	Oral	600 Mg, Every 3-4 Hours Regularly	Pfizer
	Ibuprofen	S	Oral	600 Mg, Q4h	Pfizer
	Ibuprofen	S	Oral	600 Milligram	Pfizer
	Ibuprofen	S	Oral	600 Milligram, Qd	Pfizer
	Ibuprofen	S	Oral	Unk Unk, Qd	Pfizer
	Methotrexate Sodium	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5mg, 4 Times/Wk, .1096mg, 4 In 1 Years, .1315mg, 4 In 1 Years, 10 Mg, 12mg, 17.5mg, 4	Pfizer

			Times/Wk, 1	
Methotrexate Sodium	S	Unknown	25 Milligram, Qd	Pfizer
Celebrex	S	Oral	200 Milligram, Bid	Pfizer
Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Pfizer
Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Pfizer
Rituximab	S	Unknown	1000 Milligram, Bid	Pfizer
Cosentyx	S	Unknown	Unk	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Apo-Cyclosporine	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported

Humira	S	Subcutaneous	40 Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S	Oral	60 Milligram, Bid	Not Reported
Otezla	S			Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S		Unk	Not Reported
Orencia	S		Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported

Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Benadryl	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous drip	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	8 Milligram	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Uloric	C	Oral	160 Mg, 2x/Day	Not Reported

Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Oral	50 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Naproxen	C		500 Milligram	Not Reported
Cannabis Sativa	C		Unk	Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported
Risedronate Sodium	C	Oral	35 Milligram, Qwk	Not Reported

Methotrexate	C	Unknown	Unk		Not Reported
Arava	C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12447989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016284711		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Leflunomide			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12570978	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015119458		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	25 Milligram, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Positive; Synovitis; Vomiting	Orencia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Kineret	C		Unk	Not Reported
	Anakinra	C	Unknown	10 Milligram, Qd	Not Reported
	Anakinra	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12598409	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015389516		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal	Enbrel			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Oral	Lower Doses Initially & Increased Over The Yrs Around 1997		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25,Unk, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25,Unk, Qd		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day: 6 Months		Pfizer
	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	100 Milligram		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; Weight Increased	Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Indocid [Indometacin]	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, 1x/Day, For One Year	Not Reported
	Leflunomide	S	Unknown	20 Mg, Daily (For 1 Year)	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Indomethacin [Indometacin]	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram, Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Unknown	50 Mg	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported

Gold	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
Indometacin	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2x/Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Oral	Unk,Qwk	Not Reported
Folic Acid	S	Oral	5 Milligram, Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Oral	Unk, 2x/Day	Not Reported
Folic Acid Aventis	C	Oral	Unk, Weekly	Not Reported
Folic Acid Aventis	C	Oral	5 Mg, Unk	Not Reported
Cymbalta	C	Oral	30 Mg, 1x/Day (Nightly)	Not Reported
B Complex [Vitamin B Complex]	C		Unk	Not Reported
Fish Oil	C		Unk	Not Reported
Advil [Ibuprofen]	C		Unk	Not Reported
Demerol	C		Unk	Not Reported
Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12676043	EXPEDITED (15-DAY)		OT	CA-SA-2015SA146389			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated	Arava			S	Oral	20 Mg		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi

Peptide Antibody Positive; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Leflunomide	S	Unknown	Unk	Sanofi
	Plaquenil	S	Oral	400 Mg,Qd	Sanofi
	Plaquenil	S	Unknown	400 Mg, Qd	Sanofi
	Methotrexate	S	Oral	25 Mg,Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	1 Df, Qd	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	4000 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Pseudoephedrine Hydrochloride	S	Unknown	25 Mg	Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Desoximetasone	S	Cutaneous	Unk	Sanofi
	Desoximetasone	S	Subcutaneous	Unk	Sanofi
	Desoximetasone	S	Subcutaneous	Unk	Sanofi
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported

Diclofenac Sodium	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Sanofi
Hydrocortisone Acetate	S	Subcutaneous	Unk	Sanofi
Hydrocortisone Acetate	S	Unknown	Unk	Sanofi
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	5 Mg	Not Reported
Sulfasalazine	S	Oral	1 G,Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	25 Mg	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Mg	Not Reported
Hydroxychloroquine	S	Oral	Unk	Sanofi
Hydroxychloroquine	S	Oral	Unk	Sanofi
Hydroxychloroquine	S	Unknown	400 Mg, Qd	Sanofi
Hydroxychloroquine	S	Unknown	Unk	Sanofi
Folic Acid	S	Unknown	1 Mg	Not Reported
Folic Acid	S	Unknown	5 Mg	Not Reported
Folic Acid	S	Oral	25 Mg	Not Reported
Folic Acid	S	Unknown	500 Mg	Not Reported
Topicort	S	Unknown		Sanofi
Topicort	S	Unknown		Sanofi

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12682616	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016018624		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; Bone Disorder; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint Laxity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Off Label Use; Osteopenia; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	40 Milligram, Four Every One Week		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, 4 Every 1 Week		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Otezla			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Acetaminophen W/Diphenhydramine			S	Unknown	Unk		Not Reported

Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Hydrochloride Orencia	S	Unknown	200 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Hydro	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	5 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported

Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	2000 Milligram, Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Amaryl	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	Unk, Qwk	Not Reported
Methotrexate	S	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Meloxicam	C	Unknown	Unk, Qwk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Synthroid	C			Not Reported
Tylenol With Codeine No.3	C		Unk	Not Reported

Celebrex	C	Oral	200 Milligram, Bid		Not Reported
Hydromorphone Hcl	C		Unk		Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported
Codeine	C	Unknown			Not Reported
Diphenhydramine	C	Oral	50 Milligram		Not Reported
Glyburide	C	Unknown	Unk		Not Reported
Hydrochlorothiazide	C	Unknown	Unk		Not Reported
Lipitor	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk Unk, Qd		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12736972	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-073069		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Q4wk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			S	Ophthalmic	Unk Unk, Bid		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			S	Ophthalmic	2 Dosage Form, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	7 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Levothyroxine	S	Unknown	1 Dosage Form, Qd	Not Reported
Levothyroxine	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Ramipril	S	Unknown	1 Milligram, Qd	Not Reported
Ramipril	S	Unknown	1 Dosage Form	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Apo-Hydroxyquine	S	Oral	400 Milligram, Qd	Not Reported
Apo Folic	S	Unknown	Unk	Not Reported
Apo-Ramipril	S	Unknown	Unk Unk, Qd	Not Reported
Apo-Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	7 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Cosopt	S	Unknown	Unk Unk, Bid	Not Reported
Levothyroxine Sodium	S	Unknown	Unk, One Every Day	Not Reported
Altace	S	Unknown	1 Dosage Form, Qd	Not Reported
Acetaminophen	S	Oral	1000 Milligram	Not Reported
Acetaminophen With Codeine	S	Unknown	Unk Unk, Prn	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Acetaminophen;Caffeine;Dihydrocodeine	S	Unknown	Unk Unk, Prn	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk Unk, Prn	Not Reported

Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
Caffeine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Acetaminophen	C	Unknown		Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Levothyroxine	C	Unknown	Unk Unk, Qd	Not Reported
Tylenol With Codein [Caffeine;Codeine Phosphate;Paracetamol]	C	Unknown	Unk, Prn	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Meprobamate	C	Unknown	Unk	Not Reported
Caffeine;Codeine;Paracetamol	C	Unknown		Not Reported
Phosphate [Phosphoric Acid Sodium]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12913306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091788		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral;	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Pyrexia	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	12914292	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092847		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4mo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Humira			S	Unknown	40 Unk		Not Reported

Methotrexate Sodium	S	Subcutaneous	12.5 Milligram	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
Methotrexate	S	Oral	12.5 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Milligram, Cyclical	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	Unk,Qd	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Day	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Time In A Week	Not Reported
Xeljanz	C	Unknown	Unk Unk, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Amlodipine	C	Unknown		Not Reported
Cimzia	C	Subcutaneous		Not Reported
Dilaudid	C	Unknown		Not Reported
Eletriptan	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown	Sustained Release	Not Reported
Prednisone	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	13128652	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015105293		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk Unk, Qwk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Oral	1 Gram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Certolizumab			S	Unknown	200 Milligram, Q2wk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram, Qwk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Unknown	400 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	400 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk, Qwk		Not Reported

Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	640 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	640 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Qmo	Not Reported
Actemra	S	Unknown	Unk, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram	Not Reported
Actemra	S	Unknown	640 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	300 Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
Cimzia	S	Unknown	200 Milligram, Qwk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Cyclical	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	125 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
Leflunomide	S	Unknown	10 Milligram	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Rituximab	S	Intravenous (not		Not Reported

					otherwise specified)					
	Prednisone			C	Unknown	Unk				Not Reported
	Piroxicam			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	13169280	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005325		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, 4 Every 1 Week		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	13805306	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016034387		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated;	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	20 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	C	Unknown	20 Milligram, Qwk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Advil	C	Unknown	Unk	Not Reported
	Ketorolac	C	Unknown	Unk Unk, As Necessary	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	13850192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070656			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk,Cyclical		Bristol Myers Squibb

Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	10 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Actonel	C	Unknown	35 Milligram	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	13870276	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017350057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	14181590	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170158		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	40 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	14217819	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175088		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd (Or Every 24 Hours)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported

Sulfasalazine	S	Unknown	10000 Milligram, Bid		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 4 Times/Wk		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Apo-Prednisone	S	Unknown	5 Milligram, Qd		Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	14230778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017510773		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	15 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Oral	1 Gram, Qd		Pfizer
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	14310480	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050909		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Alopecia; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Asthenia; Blood Cholesterol Increased; Bursitis; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hypercholesterolaemia; Hypersensitivity; Hypertension; Infection; Infusion Related Reaction; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Malaise; Maternal Exposure During Pregnancy; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Pemphigus; Pericarditis; Peripheral Swelling; Peripheral Venous Disease; Rash;	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Cimzia	S			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	162 Milligram	Not Reported
	Arava	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S		25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Once Daily (Qd)	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
	Gold	C			Not Reported
	Plaquenil	C		Unk	Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Folic Acid	C		5 Milligram	Not Reported
	Hydroxychloroquine	S		400 Milligram	Not Reported
	Prednisone	C	Oral	15 Milligram, Once Daily (Qd)	Not Reported

Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Unevaluable Event; Vomiting	Pregabalin	C			Not Reported
	Leflunomida	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Sarilumab	S			Not Reported
	Stelara	S			Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Subcutaneous		Not Reported
	Diclofenac	S		50 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram	Not Reported
	Paracetamol	S		650 Milligram	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Rituxan	S	Subcutaneous		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tylenol [Paracetamol]	S		650 Milligram, 2x/Day (Bid)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Salazopyrin	S	Oral	2 Gram, 2x/Day (Bid)	Not Reported
	Fosamax	S	Oral		Not Reported
	Apo Prednison	S			Not Reported
	Sulfathalidine	S			Not Reported
	Hydroxychloroquine Phosphate	S		40 Milligram, Once Daily (Qd)	Not Reported
	Winpred	S	Oral		Not Reported
	Topicort Lp	S	Subcutaneous		Not Reported
	Plaquenil Sulfate	S		400 Milligram, Once Daily	Not Reported

				(Qd)	
	Calcium Carbonate W/Vitamin D [Calcium Carbonate;Colecalciferol]	C		Unk	Not Reported
	Synthroid	C			Not Reported
	Tofacitinib Citrate	C			Not Reported
	Citalopram	C			Not Reported
	Pantoprazole	C			Not Reported
	Domperidone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	14618306	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031234		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	14627389	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018099589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Celebrex	S	Unknown	Unk	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Pantoprazole	C	Unknown	Unk Unk, Tid	Not Reported
	Loperamide	C	Oral	Unk	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	14817954	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018054977		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	25 Milligram, Unk		Not Reported

Orencia	S	Subcutaneous	250 Milligram, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Gold	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	20 Milligram, Bid	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	380 Milligram	Not Reported
Actemra	S	Subcutaneous	162 Milligram	Not Reported

	Arava	S	Oral	10 Milligram, Unk	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Prednisone	C		40 Milligram, Unk	Not Reported
	Prednisone	C		250 Milligram, Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Simponi	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15056653	EXPEDITED (15-DAY)		OT	CA-ROCHE-2138287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Cimzia	S	Subcutaneous	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Winpred	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15208760	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016078449		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	1.2 Milliliter, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Upper Respiratory Tract Infection	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Simponi		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15210067	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018304801		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Ml, Qwk		Pfizer
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Mg, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15220977	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016241833		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Q2wk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Simponi			S	Subcutaneous	50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15227435	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016285040		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

Arava	S	Oral	20 Mg, 1x/Day	Not Reported
Arava	S	Oral	200 Mg, 1x/Day	Not Reported
Arava	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	400 Mg, 1x/Day	Not Reported
Apo-Hydroxyquine	S	Oral	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, 1x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Oral	200 Mg, 2x/Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Folic Acid	C	Oral	5 Milligram, Qd (6 Days Per Week)	Not Reported
Folic Acid	C	Oral	5 Milligram	Not Reported
Prednisone	C	Oral	Unk	Not Reported
Leflunomide	C	Oral	20 Milligram, Qd	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

Hydroxychloroquine	C	Oral	200 Milligram, Bid		Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qd		Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qwk		Not Reported
Tofacitinib Citrate	C		Unk		Not Reported
Methotrexate	C	Oral	20 Milligram, Qwk		Not Reported
Methotrexate	C	Oral	Unk, Q2wk		Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15246107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015106204		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Pain; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Oral Pain; Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Product Use Issue; Rheumatoid	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Enbrel			S		25 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Cyclic Q2wk		Pfizer
	Enbrel			S		25 Mg, (3 Years, Freq: 2 Week; Interval: 1)		Pfizer
	Enbrel			S		25 Mg, Cyclic Q2wk		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Pfizer
	Rituximab			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic Every Two Weeks (Duration Reported		Abbott

Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete				As 365 Units Not Reported	
	Humira	S	Unknown	200 Mg, 2x/Day	Abbott
	Humira	S	Subcutaneous	40 Mg, Unk	Abbott
	Humira	S	Subcutaneous	Unk	Abbott
	Humira	S	Subcutaneous	200 Mg, 2x/Day	Abbott
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly, Therapy Duration Reported As 61 (Unit Not Reported), (Freq: 1 Month; Interval: 1)	Not Reported
	Orencia	S		Unk, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Therapy Duration Reported As 184 (Unit Not Reported),	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, 2x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	4 Mg, Unk	Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S		1 Mg, Every 1 Day	Not Reported
Arava	S		20 Mg, Unk	Not Reported
Prednisone	S	Oral	5 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Doxycycline Hyclate	S	Unknown	50 Milligram	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Mg, Day 1 &15	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	C	Intramuscular	Unk	Not Reported
Cortisone	C	Intra-articular	Unk	Not Reported
Benadryl	C		Unk, As Needed	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Lasix	C		40 Mg, 3x/Day	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk, As Needed	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 G, Daily At Bedtime	Not Reported
Ativan	C		1 Mg,Every 1 Day	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Loperamide	C		2 Mg, 2x/Day	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk, 2x/Day	Not Reported

Norflex	C	Unknown	Unk, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Norflex	C		Unk	Not Reported
Omnaris	C	Unknown	Unk (Spray, Metered Dose)	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Dilaudid	C		4 Mg, Qd	Not Reported
Dilaudid	C	Unknown	4 Mg, Every 6 Hours	Not Reported
Dilaudid	C		4 Mg, Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Kineret	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C		100 Mg, Unk	Not Reported
Furosemide	C	Unknown	40 Mg, Three Every One Day	Not Reported
Furosemide	C	Unknown	40 Mg, 3x/Week	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk (Freq: As Needed)	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported

Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Mg, Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Mg, Unk	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C		Unk Unk, As Necessary (Freq: As Needed)	Not Reported
Plantago Ovata	C	Unknown	Unk	Not Reported
Dyclonine Hydrochloride	C		Unk	Not Reported
Orphenadrine [Orphenadrine Hydrochloride]	C	Unknown	1 Dosage Form, Bid	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram, Unk	Not Reported
Pantoloc [Pantoprazole]	C		Unk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qd	Not Reported
Methotrexate	C	Vaginal	25 Milligram, 4 Times/Wk	Not Reported
Methotrexate	C	Unknown	25 Milligram, 4 Times/Wk	Not Reported
Simponi	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15286198	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016077975		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15291621	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016315535		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Infliximab			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Kineret	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	100 Milligram, Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	30 Milligram, Qd	Not Reported
	Methotrexate Sodium	C	Unknown	25 Milligram, Qwk	Not Reported
	Cortisone Acetate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15407353	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911920		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Contraindicated Product Administered; Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Pain; Pain In Extremity; Pain In Jaw;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15470572	EXPEDITED (15-DAY)		OT	PHHY2016CA163833		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Blood	Sandostatin			S	Subcutaneous	50 Ug, Once/Single (Once-Test Dose)		Novartis
	Sandostatin			S				Novartis

Pressure Increased; Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial Neuralgia; Fatigue; Groin Pain; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Labyrinthitis; Muscle Spasms; Nausea; Nephrolithiasis; Pain; Rheumatoid Arthritis; Visual Impairment; Vomiting	Sandostatin	S				Novartis
	Sandostatin Lar	S	Intramuscular	30 Mg, Qmo		Novartis
	Sandostatin Lar	S	Intramuscular	30 Mg, Qmo		Novartis
	Sandostatin Lar	S	Intramuscular	30 Mg, Qmo		Novartis
	Atorvastatin	S	Unknown	10 Mg, Qd		Not Reported
	Bisoprolol	S	Unknown	2.5 Mg, Bid		Not Reported
	Plaquenil	S	Unknown	200 Mg, 2 Tablets Once A Day		Not Reported
	Forxiga	C	Unknown	5 Mg, Qd		Not Reported
	Dutasteride	C	Oral	0.5 Mg, Qd		Not Reported
	Tamsulosin	C	Oral	0.4 Mg, Qd		Not Reported
	Gravol	C	Unknown	1 Mg, Prn		Not Reported
	Hydromorphone	C	Unknown	1 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15524413	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017447535			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil			S		200mg, Bid		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Leflunomide	S	Oral	20 Mg, Daily	Not Reported
	Arava	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Tiaprofenic	C		300 Mg, Daily	Not Reported
	Aspirin 81	C		81 Mg, Daily	Not Reported
	Aspirin 81	C		Unk	Not Reported
	Acetylsalicylic Acid	C		81 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15554506	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018148904		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk (152.0 Days)		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk (244.0 Days)		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15583667	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372752		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	2.5 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Mg, Daily	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15629653	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2557267-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported
	Azathioprine			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15676313	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018486815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Enbrel	S	Unknown	Unk	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Xeljanz	S	Oral	5 Milligram, Qd	Pfizer
	Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Asa	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Gabapentin	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15693001	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018172161			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50 Milligram		Not Reported

	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	3 Milligram, Qd	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	50 Milligram, Unk	Not Reported
	Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15704441	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174077			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Acetaminophen	C	Unknown	Unk; 650 Milligram, Bid		Not Reported
Aluminium Acetate W/Benzethonium Chloride	C		Unk		Not Reported
Atacand	C		Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Hydrodiuril	C	Unknown	Unk		Not Reported
Neurontin	C	Unknown	600 Milligram, Tid		Not Reported
Premarin	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	650 Mg, Bid		Not Reported
Aluminium Acetate	C	Unknown	Unk		Not Reported
Benzethonium Chloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15756331	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015044981		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Celebrex			S	Unknown	200 Milligram		Pfizer
	Xeljanz			S	Oral	5 Milligram, Qd		Pfizer

Erythematosus; Vomiting; Wound	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Milligram	Pfizer
	Rituxan	S	Unknown	1 G, 1/2	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Unknown	50 Mg, Q4wk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qmo	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Monthly	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Monthly	Not Reported
	Orencia	S	Subcutaneous	150 Mg, Qwk	Not Reported
	Orencia	S	Subcutaneous	150 Gram	Not Reported
	Orencia	S	Subcutaneous	150 Mg, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Naprosyn	S	Unknown	500 Milligram, Bid	Not Reported
	Naprosyn	S	Unknown	50 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported

Cimzia	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	50 Milligram	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	40 Milligram	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Naprosyn	C		500 Mg, 2x/Day	Not Reported
	Naprosyn	C		50 Mg	Not Reported
	Celebrex	C		200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15858692	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016332250		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk, Once Every Two Weeks		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Pfizer
	Methotrexate Sodium			S	Subcutaneous	220 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram		Pfizer

Sulfasalazine	S	Oral	500 Milligram, Qd	Pfizer
Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
Xeljanz	S		5 Milligram, Qd	Pfizer
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Unknown	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Orencia	S	Unknown	75 Milligram, Qmo	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported

Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram, Q2wk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Risedronate	C	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15879571	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018014080		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported

Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Cetirizine Hydrochloride	S		10 Milligram	Not Reported
	Cetirizine Hydrochloride	S		25 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Since 4 Years	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Tofacitinib Citrate	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Intravenous drip	Unknown Dose	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Weekly (Qw)	Not Reported
	Apo Prednison	S			Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Diclofenac	S		50 Milligram	Not Reported
	Diclofenac Sodium	S			Not Reported
	Etanercept	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		0.5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		3 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported

Leflunomide	S	Oral		Not Reported
Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	15 Milligram, Once Daily (Qd)	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Paracetamol	S			Not Reported
Phthalylsulfathiazole	S			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Prednisone	S	Oral	40 Milligram	Not Reported
Prednisone	S			Not Reported
Pseudoephedrine Hcl	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Subcutaneous		Not Reported
Salazopyrine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sarilumab	S			Not Reported
Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S			Not Reported
Simponi	S	Intravenous (not otherwise specified)		Not Reported
Stelara	S	Subcutaneous	45 Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported

Sulfasalazine	S		1 Gram, Once Daily (Qd)	Not Reported
Sulfathalidine	S			Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Topicort Lp	S	Subcutaneous		Not Reported
Topicort Lp	S	Oral		Not Reported
Winpred	S	Oral		Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Salazopyrin	C			Not Reported
Adalimumab	S		40 Milligram	Not Reported
Tofacitinib	S		5 Milligram, Once Daily (Qd)	Not Reported
Tofacitinib	S	Oral	5 Milligram, Weekly (Qw)	Not Reported
Abatacept	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Arava	S			Not Reported
Folic Acid	S	Subcutaneous	1 Milligram	Not Reported
Stelara	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Apremilast	S		3 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Once Daily (Qd)	Not Reported
Desoximetasone	S	Subcutaneous		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Ustekinumab	S	Intravenous (not	45 Milligram	Not Reported

			otherwise specified)		
	Orencia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	20 Milligram	Not Reported
	Leflunomide	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Xeljanz	C			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Desoximetasone	S			Not Reported
	Tofacitinib	C			Not Reported
	Diclofenac	C			Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Abatacept	S	Subcutaneous		Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Alendronate Sodium;Alendronic Acid	S			Not Reported
	Caffeine;Codeine;Paracetamol	C			Not Reported
	Sulfasalazine	C			Not Reported
	Hydrocortisone Acetate	S			Not Reported
	Acetaminophen;Dextropropoxyphene	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15933276	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655651-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol	C		Not Reported
	Codeine	C		Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15962088	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016521103		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Infliximab			S	Intravenous (not otherwise specified)	400 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, 1 Every 1 Week		Pfizer
	Methylprednisolone			S	Unknown	80 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, 1 Every 8 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Humira	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	200 Mg, Q2wk	Not Reported
	Certolizumab Pegol	S	Unknown	200 Mg, Q2wk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Erelzi [Etanercept]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	15980078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2264569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	16126100	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027156		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Voltaren [Diclofenac]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	16228158	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2019AP012003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis;	Acetaminophen			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported

Weight Increased; Wheelchair User	Prednisone		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Apotex
	Indomethacin /00003801/		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Statex /00036302/		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Morphine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	16584896	EXPEDITED (15-DAY)		OT	PHHY2019CA120870		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Cough; Lower Respiratory Tract Infection; Malaise; Pain; Thyroid Disorder; Upper Respiratory Tract Infection	Cosentyx			S	Subcutaneous	150 Mg, Qw		Novartis
	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Novartis
	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Novartis
	Cosentyx			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Aleva			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	16797403	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17367375	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020048559		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous	Unk	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Desoximetasone	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17399645	EXPEDITED (15-DAY)		DS, HO, LT	CA-ROCHE-2538087		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Abatacept	S	Intravenous drip		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5.0 Months	Not Reported
	Infliximab	S	Unknown	9.0 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	3.0 Years, Kineret 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Kineret	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10.0 Years	Not Reported
	Methotrexate	S			Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
Orencia	S	Respiratory (inhalation)		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Oral		Not Reported
Triamcinolone Acetonide	S			Not Reported
Gamastan	S	Intramuscular		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous	62.0 Days	Not Reported
Adalimumab	S			Not Reported
Anakinra	S	Subcutaneous		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17432621	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011197		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Supeudol	C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17533248	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309558		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Loss Of Personal Independence In Daily Activities; Nausea; Off Label Use; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rheumatoid Arthritis; Sleep Disorder; Uveitis	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Otezla	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sirukumab	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Mycophenolate Sodium	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Tocilizumab	S	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17533403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243621		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Cerebrovascular Accident; Crohn'S Disease; Diverticular Perforation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Insomnia; Joint Swelling; Knee	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gabapentin			S	Unknown			Not Reported

Arthroplasty; Lower Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Pain; Peripheral Swelling; Product Use In Unapproved Indication; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Perindopril	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cosentyx	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Otezla	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Asa	S	Unknown		Not Reported
	Calcium /00060701/	S	Unknown		Not Reported
	Fosinopril	S	Unknown		Not Reported
	Fosinopril	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Morphine	S	Unknown		Not Reported
	Synthroid	S	Unknown		Not Reported
	Tylenol /00020001/	S	Unknown		Not Reported
	Vitamin D /00107901/	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Calcium Carbonate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Morphine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17566404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318840		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Simponi			S	Subcutaneous			Not Reported

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Simponi	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Actemra	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Rituximab	S	Intravenous drip		Not Reported

	Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran /00001501/	C	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Vitamin D3	C	Oral	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Gold	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17594233	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181045570		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Resistance; Herpes Zoster; Off Label Use; Pneumonitis; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)	
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S		Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

	Arava	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17594574	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colonic Abscess; Drug Ineffective; Pruritus	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	350 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Gold			C	Intramuscular	50 Milligram		Not Reported
	Leflunomide			C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17605650	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332795		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bedridden; Crying; Drug Ineffective	Simponi	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Ergocalciferol	C		Not Reported
	Folinic Acid	C		Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17605651	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332787		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prevacid		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17605713	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332775		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	For 3 Years		Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	11 Years		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous drip		Not Reported
	Sulfasalazine	S	Oral	4 Years	Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Gold	C	Unknown		Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Codeine Phosphate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Pregabalin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17611349	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20151008546		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Paroxetine Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17667419	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200409451		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Simponi			S	Subcutaneous			Not Reported
Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
Arthralgia; Arthropathy;	Actemra			S	Subcutaneous			Not Reported
Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Chloraprep			S		Topical		Not Reported
	Chlorhexidine Gluconate			S	Unknown	Oral Rinse		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Weight Increased; Wound	Leflunomide	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Oxycodone Terephthalate	S	Unknown		Not Reported
	Oxycodone And Acetaminophen	S	Unknown		Not Reported
	Periogard	S	Buccal	Alcohol Free	Not Reported
	Sulfamethoxazole	S			Not Reported
	Sulfamethoxazole And Trimethoprim	S			Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Cortisone	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported

Methotrexate	S	Oral	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Topicort /00028604/	S	Cutaneous	Not Reported
Chlorhexidine	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Reactine /00884302/	C	Unknown	Not Reported
Cetirizine Hydrochloride	C	Unknown	Not Reported
Desogestrel And Ethinylestradiol	C		Not Reported
Ibuprofen	C	Unknown	Not Reported
Pantoloc /01263201/	C		Not Reported
Pantoprazole Sodium	C	Oral	Not Reported
Paracetamol/Codeine	C		Not Reported
Tylenol /00020001/	C		Not Reported
Tylenol With Codeine	C		Not Reported
Atasol /00020001/	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Plaquenil /00072602/	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Arava	C	Oral	Not Reported
Pantoprazole	C		Not Reported
Marvelon 28	C		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17740634	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017728		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	200 Milligram (Two Every Two Days)		Apotex
	Hydroxychloroquine			S	Oral	200 Milligram		Apotex
	Apo-Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Q.M.T.		Apotex
	Apo-Leflunomide			S	Unknown	200 Milligram, Qd		Apotex
	Apo-Prednisone			S	Oral	20 Nanogram		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.I.W		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk. Therapy Duration 823 Unit Unspecified		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Milligram, Q.I.W		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Orencia	S	Unknown	200 Milligram	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	200 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Tylenol /00020001/	S	Unknown	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Subcutaneous	2000 Milligram	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	25 Dosage Form, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	Unk Unk, Q.I.W	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Q.Wk.	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Mg, Q.12h	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Milligram, Qd	Not Reported
Tylenol	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17856381	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200535384		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vulvovaginal Dryness; Weight Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cellcept /01275102/			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Lyrica	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Ciclosporin	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Pregabalin	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Meloxicam	C	Oral	Not Reported
	Prednisolone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17856875	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200537323		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Headache; Herpes Zoster; Infection; Irritable Bowel Syndrome; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Malaise; Nasopharyngitis; Nausea; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Pruritus; Rash; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Stress; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

Anakinra	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dexamethasone	C	Intramuscular	Not Reported
Dilaudid	C	Intramuscular	Not Reported
Diphenhydramine Hydrochloride	C	Intramuscular	Not Reported
Diphenhydramine Hydrochloride	C		Not Reported
Furosemide	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Norflex /00018303/	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Triamcinolone Acetonide	C	Intra-articular	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported
Arava	C		Not Reported
Desoximetasone	C	Oral	Not Reported
Pantoprazole Sodium Anhydrous	C		Not Reported
Benadryl /00000402/	C		Not Reported
Kenalog /00031902/	C		Not Reported
Lasix /00032601/	C		Not Reported

Morphine Sulfate	C			Not Reported
Pantoloc /01263201/	C			Not Reported
Prednisone	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Darifenacin	C	Unknown		Not Reported
Diphenhydramine	C	Unknown		Not Reported
Folic Acid	C	Oral		Not Reported
Metoclopramide	C			Not Reported
Ondansetron	C	Oral		Not Reported
Salazopyrin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17857390	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043618		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Erelzi [Etanercept]	S	Subcutaneous			Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
Prednisone	C	Unknown	30 Milligram, Qd		Not Reported
Desoximetasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17865064	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044295		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Cephalexin [Cefalexin]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17896693	EXPEDITED (15-DAY)		OT	NVSC2020DE164916		46 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Decreased; Blood Lactate Dehydrogenase Increased; Haematocrit Decreased; Haemoglobin Decreased; Leukopenia; Mean Cell Haemoglobin; Red Cell Distribution Width Increased; Rheumatoid Arthritis	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17901628	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609676		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Azathioprine	S		Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Celebrex	S	Unknown	Not Reported
Celebrex	S	Oral	Not Reported
Celecoxib	S	Oral	Not Reported
Celecoxib	S		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Oral	Not Reported
Panadeine Co	C		Not Reported
Altace	C		Not Reported
Altace	C		Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Apo-Gabapentin	C		Not Reported
Atorvastatin Calcium	C	Oral	Not Reported
Atorvastatin Calcium	C	Unknown	Not Reported
Cipralex /01588501/	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Conjugated Estrogens	C		Not Reported
Conjugated Estrogens	C		Not Reported
Cymbalta	C		Not Reported
Cymbalta	C		Not Reported
Cymbalta	C		Not Reported
Escitalopram	C		Not Reported
Estrace	C		Not Reported
Gabapentin	C	Oral	Not Reported

Gabapentin	C			Not Reported
Hydrochlorothiazide	C			Not Reported
Hydromorphone Hydrochloride	C	Oral		Not Reported
Hydromorphone Hydrochloride	C	Oral		Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc /01263204/	C			Not Reported
Shark-Liver Oil	C			Not Reported
Tapentadol Hydrochloride	C			Not Reported
Mupirocin	C	Topical		Not Reported
Tramacet	C	Oral		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17976421	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-052190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18028673	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-GSH201903-000763			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Increased Tendency To Bruise; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Platelet Count Decreased; Rheumatoid Arthritis; Therapy Interrupted	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Kevzara			S	Subcutaneous	200 Mg/1.14ml Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18048547	EXPEDITED (15-DAY)		HO	NVSC2020IT197863		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Erythema; Off Label Use; Rash Maculo-Papular	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Novartis
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18050770	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200716008			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Gold	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rosuvastatin Calcium	S	Oral	5 Milligram, Bid	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18055427	EXPEDITED (15-DAY)		OT	CA-009507513-2007CAN006945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Remeron			S	Unknown	15 Milligram		Merck
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S	Unknown	Dosage Form: Not Specified		Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram; Dosage Form: Not Specified		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18177093	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020163364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Liver Injury; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk Unk, Unknown		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg, Unknown		Glaxosmithkline
	Calcium			S	Unknown	Unk Unk, Unknown		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Ascorbic Acid			S	Unknown	Unk		Glaxosmithkline
	Calcium Glubionate			S	Unknown	Unk		Glaxosmithkline
	Colecalciferol			S	Unknown	Unk		Glaxosmithkline
	Calcium Carbonate			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cosentyx			S	Endocervical	Unk Unk, Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Methotrexate			S	Intracardiac	Unk Unk, Unknown		Not Reported
	Actemra			S	Intracardiac	Unk		Not Reported
	Arava			S	Endocervical	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Endocervical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Intracardiac	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

Phthalylsulfathiazole	S	Intracardiac	Unk		Not Reported
Plaquenil	S	Endocervical	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Alendronic Acid	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Quetiapine	C	Unknown	Unk Unk, Unknown		Glaxosmithkline
Pantoprazole	C	Unknown	Unk Unk, Unknown		Glaxosmithkline
Ramipril	C	Unknown	Unk		Glaxosmithkline
Calcium Gluconate	C	Unknown	Unk Unk, Unknown		Not Reported
Pantoprazole Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18192062	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-05015		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Single		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Qd		Lupin
	Azithromycin			S	Oral	500 Milligram, Qd		Lupin
	Azithromycin			S	Oral	250 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Oral	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin

Methylprednisolone	S	Intravenous (not otherwise specified)	125 Milligram, (One Dose)		Lupin
Methylprednisolone	S	Intravenous (not otherwise specified)	40 Milligram, Bid		Lupin
Methylprednisolone	S	Intravenous (not otherwise specified)	20 Milligram, Qd (Tapered Over 5 Days0		Lupin
Prednisone	S	Unknown	40 Milligram, Bid		Not Reported
Heparin	S	Subcutaneous	5000 Unit, Bid		Not Reported
Tylenol	S	Unknown	Unk		Not Reported
Furosemide	S	Intravenous (not otherwise specified)	20 Milligram		Not Reported
Beclomethasone Dipropionate Monohydrate	S	Unknown	12 Milligram, Qd (Every 24 Hour)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18204130	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025561			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Actemra			S	Unknown	8 Mg		Not Reported
	Actemra			S	Unknown	8 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Amitriptyline	C	Unknown		Not Reported
Arava	C			Not Reported
Calcium Carbonate	C	Unknown		Not Reported
Cymbalta	C		Unk	Not Reported
Elavil	C			Not Reported
Hydrochlorothiazide	C			Not Reported
Imitrex	C			Not Reported
Lyrica	C	Unknown		Not Reported
Premarin	C			Not Reported
Sumatriptan Succinate	C			Not Reported
Tenormin	C			Not Reported
Xeljanz	C	Unknown		Not Reported
Amitriptyline Hydrochloride	C	Unknown		Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Cymbalta	C	Unknown		Not Reported
Elavil	C	Unknown		Not Reported
Hydrochlorothiazid	C			Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Imitrex	C	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
Premarin	C	Unknown		Not Reported
Sumatriptan	C			Not Reported
Tenormin	C	Unknown		Not Reported

	Tofacitinib			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18251471	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181346			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	5 Mg		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Weekly (Qw)		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	Unk, Once Daily (Qd)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
Alendronic Acid	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Caffeine + Codeine + Paracetamol	C	Unknown	Unk	Glaxosmithkline
Sulfasalazine	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Atasol (Acetaminophen + Caffeine + Codeine)	C	Unknown	Unk	Not Reported
Salazopyrina	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18253093	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181674			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Ascorbic Acid			S	Unknown	Unk		Glaxosmithkline
	Calcium Glubionate			S	Unknown	Unk		Glaxosmithkline
	Calcium Carbonate			S	Unknown	Unk		Glaxosmithkline
	Calcium			S	Unknown	Unk		Glaxosmithkline
	Colecalciferol			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Intracardiac	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Alendronic Acid			S	Intracardiac	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported

	Phthalylsulfathiazole	S	Intracardiac	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Intracardiac	Unk	Not Reported
	Fosamax	S	Intracardiac	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
	Actemra	S	Intracardiac	Unk	Not Reported
	Quetiapine Fumarate	C	Unknown	Unk	Glaxosmithkline
	Ramipril	C	Unknown	Unk	Glaxosmithkline
	Pantoprazole Sodium	C	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Calcium Gluconate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18253706	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181461		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	25 Mg		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline

Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Hydrocortisone	S	Oral	Unk	Glaxosmithkline
	Arava	S	Oral	20 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	1 Dosage Form	Not Reported
	Methotrexate	S	Oral	25 Milligram, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Once Daily (Qd)	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Alendronic Acid	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported

Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)		Not Reported
Sulfasalazine	S	Oral	1 Gram		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Topicorte	S	Unknown	Unk		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Paracetamol + Codeine Phosphate	C	Unknown	Unk		Glaxosmithkline
Caffeine Citrate	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported
Atasol (Paracetamol)	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18253981	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020181367		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	25 Mg		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Hydrocortisone Sodium Succinate			S	Oral	Unk		Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Cutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline

Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Subcutaneous	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Oral	25 Milligram	Glaxosmithkline
	Folic Acid	S	Oral	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	500 Milligram	Glaxosmithkline
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Glaxosmithkline
	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Hydrocortisone	S	Oral	Unk	Glaxosmithkline
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Df	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported

Alendronate Sodium	S	Oral	Unk Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Phthalylsulfathiazole	S	Oral	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	5 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram	Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Caffeine + Codeine Phosphate + Paracetamol	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18254336	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181725		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S			Glaxosmithkline
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Cortisone Acetate	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported

Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	40 Milligram, Once Daily (Qd)	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	100 Milligram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk, 2x/Day (Bid)	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Prednisone	S	Oral	40 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

Diclofenac Potassium	C	Unknown	Unk		Glaxosmithkline
Diclofenac	C	Unknown	50 Milligram		Glaxosmithkline
Diclofenac Sodium	C	Unknown	50 Milligram		Glaxosmithkline
Salazopyrin	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18274780	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20200921577		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol			S	Unknown	500mg		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium W/Salbutamol			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18286769	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202009008633			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Circulatory Collapse; Fatigue; Headache; Lethargy; Nausea	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Dienogest/Ethinylestradiol			S	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18286898	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-261098		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18286913	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-261301		2 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Hydroxychloroquine			S	Unknown	6.5 Milligram/Kilogram, Daily		Sun
	Cefepime			C	Unknown	Unk Unk, Bid (50 Mg/Kg/Q.)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287065	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20200921515		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Omeprazole Magnesium			S	Oral			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported

Alendronate Sodium	S	Unknown	Not Reported
Atorvastatin Calcium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Furosemide	S	Unknown	Not Reported
Ipratropium Bromide W/Salbutamol Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287277	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075322		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported

	Sulfate]									
	Prednisone			S	Unknown	Unk				Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Rituxan			S	Unknown	Unk				Not Reported
	Simponi			S	Subcutaneous	Unk				Not Reported
	Sulfasalazine			S	Oral	1000 Milligram				Not Reported
	Sulfathalidine			S	Unknown	Unk				Not Reported
	Diclofenac			C	Unknown	Unk				Not Reported
	Salazopyrin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287347	EXPEDITED (15-DAY)		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06149		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Levetiracetam			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	250 Milligram Qd (Pulse Dose)		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Clonazepam			S	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287427	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06152		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	1000 Milligram, Qd		Lupin
	Levetiracetam			S	Unknown	Unk		Lupin
	Valproic Acid			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Propofol			C	Unknown	Unk		Not Reported
	Propofol			C				Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Dexmedetomidine			C	Unknown	Unk		Not Reported
	Cisatracurium Besilate			C	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Midazolam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287740	EXPEDITED (15-DAY)		OT	NVSC2020CA254048			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased;	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Diclofenac			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	25 Mg		Not Reported

Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Unknown	4 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Alendronic Acid	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287794	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06064		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Ceftriaxone			S	Unknown	Unk		Lupin
	Doxycycline			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	600 Milligram, Qd		Lupin
	Immunoglobulin G Human			C	Intravenous (not otherwise specified)	40 Gram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287859	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016130405		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Asthma; Blood Triglycerides Increased; Blood Urea Increased; C-Reactive Protein Increased; Calcinosis; Crystal Urine Present; Drug Ineffective; Dyspepsia; Eosinophil Count Decreased; Fatigue; Ill-Defined Disorder; Lymphocyte Count Abnormal; Osteoarthritis; Osteosclerosis; Pain; Red Blood Cell Sedimentation Rate Increased; Sleep	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	772 Milligram, Qmo		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Apnoea Syndrome; Sleep Disorder; Synovitis; Tendonitis	Otezla	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Celebrex	C	Unknown	100 Mg, Qd	Not Reported
	Depo-Medrol	C	Unknown	Unk	Not Reported
	Aleve	C	Unknown	Unk	Not Reported
	Robax	C	Unknown	Unk	Not Reported
	Prednisone	C		15 Mg, Qd	Not Reported
	Naproxen	C		Unk	Not Reported
	Tylenol Extra Strength	C		650 Mg, Unk, Prn	Not Reported
	Nexium	C		40 Mg, Qd	Not Reported
	Ventolin	C		Unk, Prn	Not Reported
	Vitamin B 12	C		1000 Mg, Qd	Not Reported
	Vit D	C		Unk Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288045	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-20_00010841		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Hypersensitivity; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Meloxicam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288150	EXPEDITED (15-DAY)		DE	CA-ASTRAZENECA-2020SF19536		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Losec			S	Oral	20.0mg Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium Bromide And Salbutamol Sulphate Inhalation Solution			S	Unknown			Not Reported
	Lasix			S	Unknown	40.0mg Unknown		Not Reported
	Lipitor			S	Unknown	10.0mg Unknown		Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown	10.0mg Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown	500.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288217	EXPEDITED (15-DAY)		OT	CA-SA-2020SA250559			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Drug Ineffective; Drug Intolerance; Headache; Inflammation; Leukopenia; Ocular Toxicity; Unevaluable Event	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		Up To 25 Mg Weekly		Not Reported
	Hydroxychloroquine			S				Sanofi
	Plaquenil			S		Unk		Sanofi
	Humira			S				Not Reported
	Synthroid			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288733	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020361999		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Zinc Sulfate			S		Unk		Not Reported
	Vitamin C Acid			S		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18289005	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28905		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Hepatitis;	Brenzys			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Loss Of Personal Independence In Daily Activities	Plaquenil		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine		C	Unknown	Unknown	Not Reported
	Synthroid		C	Unknown	Unknown	Not Reported
	Folic Acid		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18289328	EXPEDITED (15-DAY)		DE	CA-ASTRAZENECA-2020SF19388		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Losec			S	Oral	20.0mg Unknown		Not Reported
	Metformin			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Furosemide			S	Unknown	40.0mg Unknown		Not Reported
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Not Reported
	Lipitor			S	Unknown	10.0mg Unknown		Not Reported
	Nitrazadon			S	Unknown	10.0mg Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown	500.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18290217	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016305305		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug	Enbrel			S	Unknown	Unk		Unknown
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Rituxan			S	Intravenous (not	1 Df, Unk		Not Reported

Hypersensitivity; Drug Ineffective; Loss Of Personal Independence In Daily Activities	Rituxan	S	Unknown	otherwise specified) Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Orencia	S	Unknown	125 Mg, Weekly	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18290268	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2020M1079883			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Pain In Extremity; Rheumatoid Arthritis	Synthroid			S	Oral	175 Microgram, Qd (1 Every 1 Day)		Mylan
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (2 Every 1 Days)		Mylan
	Arava			S	Oral	Unk		Mylan
	Methotrexate			S	Oral	15 Milligram, Qw (1 Every 1 Week)		Mylan
	Prednisone			C		5 Milligram, Qd (1 Every 1 Days)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18290393	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020362275		37 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Azithromycin			S		250 Mg, 1x/Day		Pfizer
	Methylprednisolone Sodium			S		60 Mg, 1x/Day		Pfizer

Increased; Hepatic Failure; Off Label Use; Product Use In Unapproved Indication	Succinate					
	Kaletra	S		400/100 Mg, 2x/Day		Not Reported
	Dolquine	S		200 Mg, 2x/Day		Not Reported
	Omeprazol [Omeprazole]	C	Oral	20 Mg		Not Reported
	Simvastatine	C	Oral	20 Mg		Not Reported
	Hidroferol	C		Unk Unk, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18290457	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020362320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Milligram		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Sulfasalazine			S	Oral	1000 Gram, Bid		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18290516	EXPEDITED (15-DAY)		HO	NL-JNJFOC-20200916815			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Neoplasm; Cardiovascular Disorder; Fatigue; Gastrointestinal	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Disorder; Infection; Injection Site Reaction; Musculoskeletal Disorder; Neoplasm Malignant; Skin Reaction			otherwise specified)	
	Stelara	S	Subcutaneous	Not Reported
	Tremfya	S	Unknown	Not Reported
	Tremfya	S		Not Reported
	Tremfya	S		Not Reported
	Adalimumab	S	Unknown	Not Reported
	Adalimumab	S		Not Reported
	Adalimumab	S		Not Reported
	Etanercept	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Secukinumab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Vedolizumab	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Dupilumab	S	Unknown	Not Reported
	Canakinumab	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Natalizumab	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Methylpredisolone	S		Not Reported
	Hydrocortisone	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Mesalazine	S	Unknown	Not Reported
	Mercaptopurine	S	Unknown	Not Reported
	Tioguanine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18290735	NON-EXPEDITED		OT	MA-LUPIN PHARMACEUTICALS INC.-2020-05758		42 YR	Female	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Lupin
	Hydroxychloroquine Sulfate			S				Lupin
	Hydroxychloroquine Sulfate			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18290798	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020150839		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram (1 Every 12 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18291353	EXPEDITED (15-DAY)		HO	NVSC2020BR256383		28 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication	Azithromycin			S	Unknown	500 Mg, Qd		Novartis
	Oseltamivir Phosphate			S	Unknown	75 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Bid For Hve Days		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G		Not Reported

	Heparin			S	Unknown	40 Iu			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18291501	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075869		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram		Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18291895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported

Methotrexate	S	Unknown			Not Reported
Mycophenolate Mofetil	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Piroxicam	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18291995	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3573004-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Faeces Soft; Infection	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported
	Salofalk			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292292	EXPEDITED (15-DAY)		DE	US-FRESENIUS KABI-FK202009630		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Venous Thrombosis; Off Label Use	Azithromycin (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported

	No Drug Name	C	Oral	Estrogen-Containing Oral Contraceptives	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292393	EXPEDITED (15-DAY)		DE	US-FRESENIUS KABI-FK202009631		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Venous Thrombosis; Off Label Use	Azithromycin (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292700	EXPEDITED (15-DAY)		OT	NVSC2020CA254032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint	Etanercept			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	50 Milligram		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported

Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292711	EXPEDITED (15-DAY)		OT	NVSC2020CA253951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Diclofenac	S	Unknown	50 Mg	Novartis
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Alendronate Sodium Trihydrate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292733	EXPEDITED (15-DAY)		DS, OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2020AST000311		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling;	Diclofenac Potassium			S	Unknown	Unk		Assertio Therapeutics
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	3011.2 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2912 Mg, Unk		Not Reported
	Apo-Prednisone			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Not Reported
	Chlorhexidine			S	Topical	Unk		Not Reported
	Chlorhexidine Gluconate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortison			S	Topical	25 Mg, Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Unk	Not Reported
	Periogard	S	Buccal	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Unk	Not Reported
	Prednisone	S	Oral	7.5 Mg, Unk	Not Reported
	Pseudoephedrine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
	Topicort /00028604/	S	Cutaneous	Unk	Not Reported

	Xeljanz	S	Unknown	10 Mg, Unk	Not Reported
	Atasol /00020001/	C		Unk	Not Reported
	Cetrizine	C		Unk	Not Reported
	Desogestrel/Ethinylestradiol	C		Unk	Not Reported
	Ibuprofen	C		Unk	Not Reported
	Pantoloc /01263201/	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Salazopyrin	C		Unk	Not Reported
	Tylenol /00020001/	C		Unk	Not Reported
	Tylenol With Codeine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	11579040	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2015030469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During	Cimzia			S	Subcutaneous			Ucb
	Cetirizine Hydrochloride			S		25 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Apo-Folic Acid			S	Oral	5 Milligram		Not Reported
	Apo-Hydroxyquine			S		400 Milligram, Once Daily (Qd)		Not Reported
	Cetirizine			S		10mg		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Weekly (Qw)		Not Reported

Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Sulfasalazine	S	Oral	1 G, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S		Unk, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	Unk, Once Daily (Qd)	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S		10 Milligram	Not Reported

Diclofenac Sodium	S		Unk	Not Reported
Tofacitinib Citrate	S		10 Milligram, Once Daily (Qd)	Not Reported
Cortisone Acetate	S	Topical	25 Mg	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Atasol	C			Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Golimumab	S		Unk	Not Reported
Stelara	S			Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Paracetamol	S			Not Reported
Sarilumab	S			Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous		Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous		Not Reported
Xeljanz	S		5 Milligram	Not Reported
Salazopyrin	S			Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S		20 Milligram	Not Reported
Tofacitinib	S		10 Milligram, Once Daily (Qd)	Not Reported
Alendronate Sodium	S	Oral		Not Reported
Cortisone Acetate	S		25 Milligram	Not Reported
Cortisone Acetate	S		5 Milligram	Not Reported
Phthalylsulfathiazole	S		1000 Milligram	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Diclofenac	S			Not Reported
Diclofenac Potassium	S			Not Reported
Paracetamol With Codeine	C			Not Reported

Phosphate					
Caffeine Citrate	C				Not Reported
Sulfasalazine	C				Not Reported
Desoximetasone	S	Subcutaneous			Not Reported
Desoximetasone	S				Not Reported
Folic Acid	S	Oral	25 Milligram		Not Reported
Folic Acid	S				Not Reported
Hydrocortisone Acetate	S				Not Reported
Rituximab	S		Unk		Not Reported
Sulfasalazine	S	Oral	500 Milligram		Not Reported
Atasol [Paracetamol]	C				Not Reported
Topicort Lp	S				Not Reported
Cortisone	S	Oral	5 Milligram		Not Reported
Actemra	S				Not Reported
Topicorte	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	11626328	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2015032127		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adjustment Disorder With Depressed Mood; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal	Cimzia			S	Subcutaneous	Dosage Form: Solution		Ucb
	Cimzia			S				Ucb
	Cetirizine Hydrochloride			S		10 Mg, Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Ucb
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Cetirizine Hydrochloride			S	Oral	25 Milligram		Ucb
	Zyrtec-D			S		10 Mg, Unk		Not Reported
	Zyrtec-D			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Controlled Release Tablets		Not Reported
	Cetirizine Hydrochloride,			S				Not Reported

Ulcer Perforation; Fatigue; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infection; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Range Of Motion Decreased; Joint Swelling; Maternal Exposure During Pregnancy; Memory Impairment; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Pericarditis; Prescribed Overdose; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Sleep Disorder; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Noncompliance; Type 2 Diabetes Mellitus; Vomiting; Walking Aid User; Weight Decreased; Wheezing; Wound; Wound Infection	Pseudoephedrine Hydrochloride	S			
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		25 Milligram, Ointment	Ucb
	Cirrus	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S			Not Reported
	Folic Acid	S	Oral	5 Mg, Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S	Subcutaneous	1 Milligram	Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S	Oral	500 Milligram	Not Reported
	Folic Acid	S	Oral	25 Milligram	Not Reported
	Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S	Oral	5 Milligram	Not Reported
	Prednisone	S	Oral	1 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Fosamax	S	Subcutaneous		Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Sulfathalidine	S		Dosage Form: Unspecified	Not Reported

Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	4 Unk	Not Reported
Humira	S	Sunconjunctival	Unk Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S		25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported

Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		400 Milligram, Once Daily (Qd)	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		1 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		10 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Diclofenac Potassium	S		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Adalimumab	S		Unk	Ucb
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S			Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S			Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Oral		Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Desoximetasone	S		25 Milligram	Not Reported
Desoximetasone	S		Cutaneous Route	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac	S			Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S			Not Reported
Sarilumab	S			Not Reported

Topicort	S	Cutaneous		Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S		Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Golimumab	S			Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S			Not Reported
Cosentyx	S		Unk	Not Reported
Acetaminophen	S	Oral	20 Milligram	Not Reported
Cetirizine Hydrochloride	S		10 Milligram	Not Reported
Naproxen Sodium	S		500 Milligram	Not Reported
Salazopyrin	C		Unk	Not Reported
Atasol	C		Unk	Not Reported
Tofacitinib Citrate	C			Not Reported
Ibuprofen	C			Not Reported
Ibuprofen	C			Not Reported
Prinivil	C			Not Reported
Prinivil	C			Not Reported
Cholecalciferol	C			Not Reported
Cholecalciferol	C			Not Reported
Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	C			Not Reported
Caffeine Citrate	C			Not Reported
Sulfasalazine	C			Not Reported
Alendronate Sodium;Alendronic Acid	S			Not Reported
Leflunomide	C			Not Reported

	Caffeine Citrate;Codeine Phosphate;Paracetamol	C			Not Reported
	Colecalciferol	C			Not Reported
	Lisinopril	C			Not Reported
	Kevzara	S	Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	12185482	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016145185		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 To 12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 To 12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	1 Dosage Form, Qwk		Pfizer
	Sulfasalazine			S	Oral	2.5 G, Daily		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Oral	2.5 Gram		Pfizer
	Sulfasalazine			S	Unknown	2.5 Milligram, Qd		Pfizer
	Gabapentin			S	Oral	100 Milligram, Bid		Pfizer
	Gabapentin			S	Unknown	100 Mg, 1 Every 2 Days		Pfizer
	Gabapentin			S	Oral	100 Milligram, Q2wk		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Celebrex			S	Unknown	Unk, Occlusive Dressing Technique		Pfizer
	Fentanyl			S	Unknown	Unk		Pfizer
	Fentanyl			S	Unknown	Unk		Pfizer

Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celecoxib	S	Oral	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 1x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, Unk	Pfizer
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Pfizer
	Plaquenil	S	Unknown	400 Mg, Daily (Qd)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	750 Milligram, Qmo	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Every 3 Weeks	Not Reported
	Myochrysine	S	Intramuscular	60 Mg, Cyclic Q3wk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Orencia	S	Subcutaneous	Unk, Qwk	Not Reported
	Orencia	S	Vaginal	750 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q3wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10mg Tablets 1-3 Tablets Every Evening	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Q4wkq	Not Reported
	Actemra	S	Oral	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, Qmo	Not Reported

Actemra	S	Unknown	8 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo Fentanyl Matrix	S		Unk	Not Reported
Apo Celecoxib	S	Oral	Unk	Not Reported
Apo Gabapentin	S		Unk	Not Reported
Apo Gabapentin	S	Oral	100 Mg, 2x/Day	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Fentanyl Matrix	S	Unknown	Unk Patch	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
Omega-3 [Salmo Salar Oil]	S	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Multivitamin	C		Unk	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
Vitamin D	C		400 Iu, Daily	Not Reported
Actonel	C		36 Mg, Qwk	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, (Every Four Weeks)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C		Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	488 Unk	Not Reported

Calcium	C		Unk	Not Reported
Fergon	C		300 Milligram, Qd	Not Reported
Fergon	C		300 Mg, 1x/Day	Not Reported
Fergon	C		Unk	Not Reported
Tylenol	C	Oral	500 Mg 2 Tabs, Od	Not Reported
Nexium	C		40 Milligram One Tab, Bid	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day At Bedtime	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day	Not Reported
Trazodone Hcl	C	Oral	50 Milligram, Qhs	Not Reported
Nasonex	C	Nasal	2 Sprays Per Nostrils, Bid	Not Reported
Nasonex	C		Unk Unk, Bid (Spray Metered Dose)	Not Reported
Nasonex	C		2 Df, 2x/Day	Not Reported
Percocet	C		1 Tab 4-6h As Needed	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		2.5mg 3-4 Times/Day	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		2.5 Mg, Qd	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
D-Alpha Tocopherol	C	Unknown		Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Iu, 1x/Day	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Df, Unk	Not Reported

Trazodone	C		Unk; 1000 Milligram, Qd	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole	C		400 Mg, 2x/Day	Not Reported
Esomeprazole	C		Unk	Not Reported
Loperamide Hydrochloride	C		2.5 Milligram	Not Reported
Ergocalciferol	C		400 International Unit, Qd	Not Reported
Ergocalciferol	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1x/Day	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclic Qh	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega 3 2100	C		1200 Mg, 2x/Day	Not Reported
Omega 3 2100	C		Unk, Q2wk	Not Reported
Genteal [Hypromellose]	C		3m Use As Directed	Not Reported
Fish Oil	C		1200 Mg, 2x/Day	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Nicotinamide	C		Unk	Not Reported
Pantoprazole	C		400 Mg, 1x/Day	Not Reported
Pantoprazole	C		40 Mg, 1x/Day	Not Reported
Pantoprazole	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Pyridoxine Hydrochloride	C		Unk	Not Reported
Sodium	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported

Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vit D3	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C		1200 Mg, 2x/Day	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk, Q2wk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Sodium Ascorbate	C		Unk	Not Reported
Thiamine Mononitrate	C		Unk	Not Reported
Vitamine C	C		Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Loperamide	C		Unk	Not Reported
Perfenazine	C	Oral	10 Milligram	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	C		Unk	Not Reported
Nortriptyline	C		Unk	Not Reported
Oxycodone And Acetaminophen	C		Unk	Not Reported
Epa Dha 720	C		Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate	C		Unk	Not Reported

Hydrochloride]				
Thiamine	C		Unk	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported
Zoledronic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	12249911	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016193745		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Productive Cough; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Humira	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Prednisone	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Warfarin	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	20 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	20 Milligram 1 Every 04 Hours	Not Reported
	Warfarin	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk (Intravenous Drip)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk (Capsule And Tablet)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	12343178	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016240466			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Actemra			S	Intravenous (not	772 Milligram, Qmo		Not Reported

			otherwise specified)		
	Apo Hydroxychloroquine	S	Oral	400 Mg, Qwk	Not Reported
	Myochrysine	S	Intramuscular	Unk, Dose Form: Solution Intramuscular	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 9 Month, Dosage Form: Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	12590294	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015336939		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Off Label Use; Product Use Issue; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis;	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S		50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Milligram, Qwk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Intravenous (not	300 Mg		Pfizer

Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased			otherwise specified)		
	Methotrexate Sodium	S	Subcutaneous	Unk	Pfizer
	Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
	Sulfasalazine	S	Unknown	500 Milligram	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Oral	1 Gram	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Lyrica	S	Unknown	Unk	Pfizer
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	640 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	Unk, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram	Not Reported
	Actemra	S	Unknown	640 Milligram	Not Reported
	Arava	S	Oral	Unk Unk, Qwk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Humira	S	Unknown	400 Milligram, Qwk	Not Reported

Humira	S	Subcutaneous	400 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Imuran	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram , Qwk (2 Years)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg, Cyclic	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	125 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
Leflunomide	S	Unknown	10 Milligram	Not Reported
Tocilizumab	S	Unknown	640 Mg, Weekly	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Piroxicam	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	12889043	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013260		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Diclofenac			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Apo-Sulfatrim			S	Unknown	Unk		Apotex
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Apotex
	Arava			S	Oral	Unk		Not Reported

Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Motrin	S	Unknown	Unk	Not Reported
	Naprosyn /00256201/	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Vitamin C /00008001/	S	Unknown	Unk	Not Reported
	Arava	S	Subcutaneous	Unk	Not Reported
	Voltaren /00372301/	S	Unknown	Unk	Not Reported
	Ascorbic Acid	S	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	13057913	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase; Aspartate	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex

Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Alendronate	S	Oral	70 Mg, Q.Wk.	Apotex
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, B.I.Wk.	Not Reported
	Enbrel	S	Unknown	50 Milligram, B.I.Wk.	Not Reported
	Codeine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Tocilizumab	S	Unknown	680 Mg, Unk	Not Reported
	Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
	Tocilizumab	S	Unknown	388 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	760 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Rituximab	S	Unknown	100 Mg, Bid	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Mg, B.I.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 11 Every Two Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported

Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Actemra	S	Unknown	680 Milligram, Q.M.T.	Not Reported
Actemra	S	Unknown	360 Mg, Q.Wk.	Not Reported
Actemra	S	Unknown	680 Mg, Q.Wk.	Not Reported
Actemra	S	Unknown	680 Milligram, Q.Wk.	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Etanercept	S	Unknown	25 Milligram, B.I.Wk.	Not Reported
Etanercept	S	Unknown	50 Milligram, Q.Wk.	Not Reported
Methotrexate	S	Oral	10 Milligram, Q.Wk.	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Prednisone	C	Unknown	10 Mg, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	13113122	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017001862		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Neoplasm Excision; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Methotrexate			S	Subcutaneous	10 To 17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 To 12.5 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 To 15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown	680 Milligram		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ciclosporin			C		150 Milligram, Qd		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	13152994	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004666		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Orencia		S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Leflunomide		S	Oral		Not Reported
	Prednisone		S	Unknown		Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Naproxen Sodium		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	13519393	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038017		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Mg		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	20 Milligram		Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram		Not Reported
Leflunomide	S	Oral	20 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
Meloxicam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	13519786	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Arava			S	Unknown	25 Mg, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	25 Mg, Qwk		Not Reported
	Myochrysine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	13822142	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016163871		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Enbrel			S	Unknown	Unk		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Advil			C	Unknown	Unk		Not Reported
	Ketorolac			C	Unknown	Unk Unk, As Necessary		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	20 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	14227318	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506298		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; Condition Aggravated;	Enbrel			S	Unknown	50 Milligram, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer

Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium		S	Subcutaneous	20 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium		S	Subcutaneous	20 Mg, Qwk	Pfizer
	Sulfasalazine		S	Unknown	1000 Milligram, Bid	Pfizer
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Bid	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	20 Milligram, Qd	Not Reported
	Humira		S	Subcutaneous	20 Milligram, Qd	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil		S	Oral	200 Milligram, Bid	Not Reported
	Prednisone		S	Oral	5 Milligram, Qd	Not Reported
	Apo-Prednisone		S	Unknown	5 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram, Bid	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	14242641	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown	Unk		Apotex
	Moxifloxacin			S	Oral	Unk		Apotex
	Avelox			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	14631653	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018102054		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Supeudol	C	Unknown	5 Mg	Not Reported
	Supeudol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	14909761	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076622		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Abatacept			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported

Leflunomide	S	Oral	20 Milligram		Not Reported
Methotrexate	S	Endocervical	25 Milligram, Qd		Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd		Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram, Qd		Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram, Qd		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Simponi	C	Unknown			Not Reported
Meloxicam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15305866	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA022013			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Actemra	S	Unknown	Unk	Not Reported
Kineret	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk (Stop Date: 17-May-2016)	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	100 Milligram, Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
Prednisone	C	Unknown	30 Milligram, Qd	Not Reported
Methotrexate Sodium	C	Unknown	25 Milligram, Qwk	Not Reported
Cortisone Acetate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15505712	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014007688		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Enbrel			S	Unknown	50 Milligram (558.0 Days)		Amgen
	Penicillin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported

Methotrexate	S	Oral	25 Mg, Unk		Not Reported
Methotrexate	S	Unknown	17.5 Unk, Unk		Not Reported
Methotrexate	S	Oral	25 Milligram, Qd		Not Reported
Sulfasalazine	S	Oral	1.5 G, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Plaquenil	C		Unk		Not Reported
Plaquenil	C	Unknown	300 Mg, Unk		Not Reported
Vitamin D	C	Unknown	Unk		Not Reported
Calcium	C		Unk		Not Reported
Tylenol	C	Unknown	Unk, As Necessary		Not Reported
Hydroxychloroquine	C		300 Mg, Unk		Not Reported
Prednisone	C	Unknown	10 Mg, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		300 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15556082	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017475999		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Infliximab			S	Unknown	Unk		Pfizer
	Lidocaine Hcl			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Cephalexin	C		500 Mg, Tid	Not Reported
	Cephalexin	C		500 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15560465	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018441493		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S		50 Milligram, Qwk (152.0 Days)		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk (244.0 Days)		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	40 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15632602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-110215			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Orencia			S	Unknown	40 Mg, Q2wk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, Qd		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral	300 Mg, Unk		Not Reported

Pantoprazole	C	Unknown	Unk		Not Reported
Zopiclone	C	Unknown	7.5 Mg, Qd		Not Reported
Folic Acid	C	Oral	2.5 Mg, Qd		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15699782	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018502371			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	3 Mg, 1x/Day		Not Reported
	Apo-Prednisone			S	Unknown	50 Mg		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	3 Milligram, Qd		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	50 Milligram, Unk		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15855189	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017546580		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Kevzara			S		Unk		Not Reported
	Kevzara			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 10 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q (Every)14 Day		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S		Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S		Unk	Not Reported
Apo-Leflunomide	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
Adalimumab	S	Subcutaneous	40 Mg	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	750 Mg, Monthly	Not Reported
Orencia	S	Unknown	Unk	Not Reported

Orencia	S	Unknown	750 Mg, Monthly		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G		Not Reported
Rituximab	S		Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, 1x/Day		Not Reported
Rabeprazole Sodium	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	15973937	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA018099			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Synovitis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	400 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, 1 Every 1 Week		Not Reported
	Methylprednisolone			S	Unknown	80 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, 1 Every 8 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q2wk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Plaquenil	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Erelzi [Etanercept]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	16071582	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05854		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Unknown			Not Reported

	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S			Not Reported
	Arava	C	Unknown	Unknown	Not Reported
	Arava	C	Oral	Unknown	Not Reported
	Arava	C	Unknown	Unknown	Not Reported
	Arava	C	Oral	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	16145460	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA019978			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	25 Mg, 2x/Week (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Not Reported

Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Etanercept	S	Unknown	25 Mg, 2x/Week	Not Reported
	Etanercept	S	Unknown	50 Mg, Weekly	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	15.5, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported

Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk (Stop Date: Jun 2008)	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Q12h	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day (Stop Date: Jan 2011)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not	1000 Mg, 1x/Day	Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks (Stop Date: 2010)	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks); (Stop Date: Apr 2012)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported

Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Milligram, Qwk	Not Reported
Actemra	S	Unknown	360 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly (Stop Date: Feb 2013)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported

Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Gold	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Prednisone	C	Unknown	10 Mg	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Cyclosporin	C	Unknown	150 Mg, 1x/Day (Stop Date: 20 Apr 2016)	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, 2x/Day	Not Reported

Xeljanz	C	Oral	11 Milligram, Qd		Not Reported
Prednisolone	C		Unk		Not Reported
Leflunomide	C	Oral	20 Mg		Not Reported
Leflunomide	C	Oral	20 Mg		Not Reported
Leflunomide	C	Unknown	20 Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Arava	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	16150154	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP010560		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Acetylsalicylic Acid			S	Oral			Not Reported
	Diclofenac Potassium			S	Unknown			Apotex
	Ibuprofen			S	Unknown			Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Naproxen			S	Unknown			Apotex
	Tramadol			S	Unknown	Unk		Apotex
	Trimethoprim/Sulfamethoxazole			S	Unknown			Apotex
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Oral			Not Reported
	Motrin [Ibuprofen]			S	Unknown	Unk		Not Reported

Naprosyn [Naproxen]	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Tramadol Hydrochloride	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	16183839	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011188		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Acetazolamide			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Apotex
	Cyclosporine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Infliximab			S	Intravenous (not otherwise specified)	Unk, Q.M.T.		Not Reported
	Infliximab			S				Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported
	Acetazolamide			C	Unknown	Unk		Not Reported
	Acetazolamide			C				Not Reported
	Alendronate			C				Not Reported
	Alendronate			C				Not Reported

Azathioprine	C	Unknown	Unk		Not Reported
Azathioprine	C				Not Reported
Calcium	C	Unknown	Unk		Not Reported
Calcium	C				Not Reported
Cyclosporin A	C	Unknown	Unk		Not Reported
Cyclosporin A	C				Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C				Not Reported
Iron	C	Unknown	Unk		Not Reported
Iron	C				Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Leflunomide	C				Not Reported
Mtx [Methotrexate]	C	Unknown	Unk		Not Reported
Mtx [Methotrexate]	C				Not Reported
Cyclosporine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	16330442	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019077665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	16731220	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1095844		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Clear Cell Renal Cell Carcinoma; Complications Of Bone Marrow Transplant; Hair Follicle Tumour Benign; Hepatosplenic T-Cell Lymphoma; Hypotension; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Pyrexia; Splenomegaly; T-Cell Lymphoma; Tachycardia; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S				Ivax
	Ciclosporin			S				Ivax
	Alendronate Sodium			S	Unknown			Actavis
	Etoposide			S	Unknown			Teva
	Etoposide			S				Teva
	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Amlodipine			S	Unknown			Teva
	Metformin			S	Unknown			Actavis
	Ferrous Fumarate			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	.7143 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S				Not Reported
	Thalidomide			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported

Etanercept	S			Not Reported
Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	33.3333 Milligram Daily;	Not Reported
Remicade	S			Not Reported
Acetazolamide	S	Unknown		Not Reported
Calcium Carbonate	S	Unknown		Not Reported
Cyclophosphamide	S	Unknown		Not Reported
Enalapril	S	Unknown		Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Insulin	S	Unknown		Not Reported
Nutropin	S	Subcutaneous		Not Reported
Protropin	S	Intramuscular		Not Reported
Ranitidine	S	Unknown		Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Testosterone	S	Unknown		Not Reported
Erelzi 25 Mg Solution For Injection In Prefilled Syringe	S	Subcutaneous		Not Reported
Erelzi 25 Mg Solution For Injection In Prefilled Syringe	S	Subcutaneous		Not Reported
Thalomid	S	Unknown		Not Reported
Etoposide	C			Not Reported
Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	C			Not Reported
Tacrolimus	C			Not Reported
Thalidomide Celgene -50 Mg Capsula Rigida - Celgene Europe Limited	C			Not Reported

Thalomid	C		Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	16802731	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019043939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			C	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17209189	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027635			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity;	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Infliximab			S		Unk		Not Reported

Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Product Use In Unapproved Indication; Synovitis	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Morphine Sulfate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Etanercept	S		Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk (Unit=Prefilled Syringe)	Not Reported
	Cimzia	S	Unknown	Unk (Unit=Prefilled Syringe)	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

Otezla	S	Unknown	Unk		Not Reported
Otezla	S	Oral	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sirukumab	S	Unknown	Unk		Not Reported
Stelara	S	Subcutaneous	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported
Golimumab	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Ustekinumab	S	Subcutaneous	Unk		Not Reported
Dilaudid	C		Unk		Not Reported
Dilaudid	C		Unk		Not Reported
Dilaudid	C		Unk		Not Reported
Wellbutrin	C		Unk		Not Reported
Wellbutrin	C		Unk		Not Reported
Wellbutrin	C		Unk		Not Reported
Bupropion Hydrochloride	C		Unk		Not Reported
Hydromorphone Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17215587	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39411		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Bronchitis; C-Reactive Protein	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported

Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S			Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Leflunomide	S			Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Desoximetasone	S	Unknown	Unknown	Not Reported
	Humira	S	Unknown	Unknown, Solution Subcutaneous	Not Reported
	Methadone	S	Unknown	Unknown	Not Reported
	Ramipril	S	Unknown	Unknown	Not Reported

Xeljanz	S	Oral		Not Reported
Calcium	C	Unknown		Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unknown	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unknown	Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Gravol Ginger	C	Unknown		Not Reported
Gravol Ginger	C	Oral		Not Reported
Morphine	C	Unknown	Unknown	Not Reported
Potassium Chloride	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Xalatan	C	Unknown	Solution Opthalmic	Not Reported
Xalatan	C	Ophthalmic	Solution Ophthalmic	Not Reported
Xalatan	C	Ophthalmic	Solution Ophthalmic	Not Reported
Xeljanz	C	Oral		Not Reported
Zingiber Officinale	C	Oral		Not Reported
Zingiber Officinale	C	Oral		Not Reported
Estrogel	C	Unknown		Not Reported
Estrogel	C	Unknown		Not Reported
Estrogel	C	Unknown	Unknown	Not Reported
Estrogel	C		Unknown	Not Reported
Baclofen	C	Unknown		Not Reported
Baclofen	C	Unknown	Unknown	Not Reported
Gravol	C	Unknown	Unknown	Not Reported

	Gravol Ginger Nighttime	C	Unknown	Unknown		Not Reported
	Levaquin	C	Unknown			Not Reported
	Tofacitinib Citrate	C	Oral			Not Reported
	Acetaminophen	C	Unknown	Unknown		Not Reported
	Jamp K20	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17688373	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP016273		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Folic Acid			S	Unknown	5000 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	25 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	1 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Alendronate			S	Oral	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1 G, Q.12h		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported

Sulfasalazine	S	Oral	1 G, Bid (Therapy Duration 365 Unit Unspecified)	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Q.12h	Not Reported
Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg, Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Reactine /00884302/	S	Unknown	10 Milligram, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unit Unspecified)	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Topicort /00028604/	S	Cutaneous	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported

Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 G, Q.12h	Not Reported
Tofacitinib Citrate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Humira	S	Sunconjunctival	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17843980	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011163		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Amlodipine	S	Oral	5 Mg, Qd	Apotex
	Amlodipine	S	Oral	Unk, Qd	Apotex
	Gliclazide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Asacol	S	Unknown	800 Mg, Tid	Not Reported
	Asacol	S	Unknown	800 Milligram Three Every Two Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Diamicron	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported

Depo-Medrol	C	Intra-articular	Unk		Not Reported
Diphenhydramine	C	Oral	50.0 Mg, Unk		Not Reported
Ebastine	C	Unknown	Unk		Not Reported
Ferrous Gluconate	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
Methylprednisolone	C	Intra-articular	Unk		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Rosuvastatin Calcium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17850537	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212789		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram (1 Every 12 Hours)		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17857451	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043185			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Prednisone	S	Oral	5 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Gram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17863104	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000469			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Neutropenia; Thrombocytopenia	Furosemide			S	Unknown	Unk		Validus
	Sarilumab			S	Subcutaneous	400 Mg, 1x		Not Reported
	Azithromycin			S	Unknown	500 Mg, Unk		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Mg, Qd		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Amiodarone Hydrochloride			S	Unknown	Unk		Not Reported
	Enoxaparin Sodium			S	Unknown	Unk		Not Reported
	Paroxetine Hydrochloride			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported

Racecadotril	C	Unk	Not Reported
Kcl	C	Unk	Not Reported
Lansoprazole	C	Unk	Not Reported
Clopidogrel	C	Unk	Not Reported
Tamsulosin	C	Unk	Not Reported
Eplerenone	C	Unk	Not Reported
Amlor	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Seresta	C	Unk	Not Reported
Hydroxyzine	C	Unk	Not Reported
Melatonine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17880650	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020223817		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk, Weekly		Unknown
	Enbrel			S	Subcutaneous	50 Milligram		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram, Bid (Intravenous (Not Otherwise Specified) Intravenous		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid Intravenous		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	750 , Milligram		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	500 Milligram (Intravenous (Not Otherwise Specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	50 Milligram, Qd		Not Reported
Prednisone	S	Oral	20 Milligram, Qd		Not Reported
Simponi	S	Subcutaneous	50 Milligram		Not Reported
Simponi	S	Unknown	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17887848	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048070			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort;	Gabapentin			S	Oral	100 Milligram, 1 Every 2 Weeks		Glenmark
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Od		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Weeks		Not Reported
	Oxycontin			S	Unknown	750 Milligram, 1 Every 1		Not Reported

Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure				Month		
	Actemra		S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month	Not Reported
	Enbrel		S	Unknown	50 Milligram, Qw	Not Reported
	Methotrexate		S	Subcutaneous	1 Dosage Form, Qw	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
	Sulfasalazine		S	Unknown	2.5 Milligram, Od	Not Reported
	Celebrex		S	Oral	Unk	Not Reported
	Nasonex		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	50 Milligram, Od	Not Reported
	Trazodone		C	Unknown	1000 Milligram, Od	Not Reported
	Tylenol /00020001/		C	Unknown	1000 Milligram, Od	Not Reported
	Zoledronic Acid		C	Unknown	Unk	Not Reported
	Aclasta		C	Intravenous (not otherwise specified)	488 Milligram (1 Every 1 Month)	Not Reported
	Trazodone Hydrochloride		C	Oral	50 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17924819	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005006127			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Neutropenia; Product Use In Unapproved Indication; Thrombocytopenia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd, Coated Tablet		Concordia
	Sarilumab			S	Subcutaneous	400 Mg, Qd		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	500 Mg		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown	Unk		Not Reported
	Amiodarone Hydrochloride			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Enoxaparin Sodium			S	Unknown	Unk		Not Reported

	Paroxetine Hydrochloride		S	Unknown	Unk	Not Reported
	Atorvastatin		S	Unknown	Unk	Not Reported
	Levothyroxine		C		Unk	Not Reported
	Alprazolam		C		Unk	Not Reported
	Racecadotril		C		Unk	Not Reported
	Kcl		C		Unk	Not Reported
	Lansoprazole		C		Unk	Not Reported
	Clopidogrel		C		Unk	Not Reported
	Tamsulosin		C		Unk	Not Reported
	Eplerenone		C		Unk	Not Reported
	Amlor		C		Unk	Not Reported
	Gabapentin		C		Unk	Not Reported
	Seresta		C		Unk	Not Reported
	Hydroxyzine		C		Unk	Not Reported
	Melatonine		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17925306	EXPEDITED (15-DAY)		DE	CA-ASTRAZENECA-2020SE78478		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Losec			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Atrovent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Metformin			S	Oral			Not Reported

Nitrazadon	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Salmeterol Xinafoate	S	Unknown	Not Reported
Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17946182	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020FR177729		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Coronavirus Infection; Cough; Covid-19 Pneumonia; Headache; Interstitial Lung Disease; Lung Opacity; Myalgia; Off Label Use; Pyrexia; Respiratory Failure; Therapeutic Response Unexpected	Rituximab			S	Parenteral	Four Infusions (375 Mg/M2) Were Weekly		Not Reported
	Rituximab			S	Unknown	500 Mg (Maintenance Therapy), Single Dose		Not Reported
	Prednisone			S	Unknown	15 Mg Daily		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg/8 Hour For 10 Days From Day #19		Not Reported
	Nebivolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	17988856	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020259743		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram, Bid (Intravenous (Not Otherwise Specified)		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Pfizer

	Sulfasalazine	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	8 Milligram/Kilogram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	50 Milligram, Qd	Not Reported
	Prednisone	S	Oral	20 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram (Intravenous (Not Otherwise Specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram	Not Reported
	Simponi	S	Unknown	50 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18000289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054784		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

Wrist Deformity	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18083046	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP014287		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Asa			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Fosinopril			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Vitamin D 3			S	Unknown	Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Calcium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18157694	EXPEDITED (15-DAY)		OT	CA-ROCHE-2656549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported

	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Topicort (Canada)	S	Subcutaneous		Not Reported
	Topicort (Canada)	S	Topical		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Salazopyrina	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18224611	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-259696		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Ceftriaxone			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Sun
	Levofloxacin			S	Unknown	500 Milligram, Daily		Ranbaxy
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18241483	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1076354		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Off Label Use; Rash	Ceftriaxone			S		Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Mylan

	Levofloxacin	S	Unknown	500 Milligram, Qd	Mylan
	Plaquenil /00072603/	S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18249007	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA025720			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Acetaminophen			S	Oral	1000.0 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600.0 Milligram, 1 Every 4 Weeks		Not Reported
	Altace			S	Unknown	1.0 Dosage Form, 1 Every 1 Days		Not Reported
	Apo-Prednisone			S	Unknown	7.0 Milligram, 1 Every 1 Days		Not Reported
	Apo-Ramipril			S	Unknown	Unk, 1 Every 1 Days		Not Reported
	Codeine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Cosopt			S	Unknown	Unk, 2 Every 1 Days		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			S	Ophthalmic	Unk, Bid		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			S	Ophthalmic	2.0 Dosage Form, 1 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Milligram, 1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Oral	400.0 Milligram, 1 Every 1		Not Reported

			Days	
Hydroxychloroquine Sulfate	S	Oral	400.0 Milligram, 1 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Levothyroxine	S	Unknown	Unk, 1 Every 1 Days	Not Reported
Levothyroxine	S	Unknown	Unk, 1 Every 1 Days	Not Reported
Levothyroxine Sodium	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks	Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400.0 Milligram, 1 Every 1 Days	Not Reported
Prednisone	S	Unknown	7.0 Milligram, 1 Every 1 Days	Not Reported
Ramipril	S	Unknown	1.0 Dosage Form, 1 Every 1 Days	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, 1 Every 1 Days	Not Reported
Tylenol	S	Unknown		Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
Acetaminophen With Codeine	C	Unknown		Not Reported
Acetaminophen, Caffeine And Dihydrocodeine Bitartrate	C	Unknown		Not Reported
Acetaminophen;Caffeine	C	Unknown		Not Reported
Caffeine	C	Unknown		Not Reported
Diphenhydramine	C	Oral	50.0 Milligram	Not Reported
Hydroxychloroquine Phosphate	C	Unknown		Not Reported
Meprobamate	C	Unknown		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
Phosphate [Phosphoric Acid Sodium]	C	Unknown		Not Reported

	Tylenol		C	Unknown	Not Reported
	Tylenol With Codein [Caffeine;Codeine Phosphate;Paracetamol]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18249013	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025734			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Mg, 1 Every 24 Hours		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	20.0 Mg 1 Every 1 Week		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1.0 G, 1 Every 24 Hours		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown	15.0 Mg, 1 Every 24 Hours		Not Reported
	Xeljanz			C	Oral	5.0 Mg, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18252764	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181412		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Intentional Product Use Issue; Joint Swelling; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Glaxosmithkline
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydrocortisone Acetate	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Cortisone Acetate	S	Topical	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S	Oral	40 Milligram	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Infusion, Solution	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Actemra	S	Subcutaneous	Pre-Filled Syringe	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Diclofenac	C	Unknown	Unk	Glaxosmithkline
Sulfasalazine	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18252870	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020181429			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic	Cetirizine Hydrochloride			S	Unknown	10 Milligram, Once Daily		Glaxosmithkline

Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound				(Qd)	
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram, Once Daily (Qd)	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Desoximetasone	S	Cutaneous	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Diclofenac	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Once Daily (Qd)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tofacitinib	S	Unknown	10 Milligram	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Hydroxychloroquine	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Phthalylsulfathiazole	S	Oral	2000 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Cutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Caffeine + Codeine +	C	Unknown	Unk	Not Reported

	Paracetamol						
	Sulfasalazine		C	Unknown	Unk		Not Reported
	Atasol (Paracetamol)		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18252873	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Folic Acid			S	Oral	25 Mg		Glaxosmithkline
	Reactine (Cetirizine Hydrochloride)			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Abatacept			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Abatacept			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	4 Mg Cutaneous Solution		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Pre Filled Syringe		Not Reported
Stelara	S	Unknown	Injection, Solution		Not Reported
Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)		Not Reported
Alendronate Sodium	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Oral	1 Gram		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Topicorte	S	Subcutaneous	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Infusion, Solution		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Actemra	S	Intravenous (not otherwise specified)	Infusion, Solution		Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18254152	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181671		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline

Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown	25 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Desoximetasone	S	Subcutaneous	Unk	Glaxosmithkline
	Cortisone Acetate	S	Unknown	25 Milligram	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Topicort	S	Subcutaneous	Unk	Glaxosmithkline
	Topicort	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Oral	5 Milligram	Glaxosmithkline
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	40 Milligram	Not Reported
	Enbrel	S	Subcutaneous	40 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	1 Dosage Form	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Hydrocortisone	S	Unknown	Unk	Not Reported

Xeljanz	S	Unknown	5 Milligram	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Oral	5 Milligram	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	5 Milligram	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18267432	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200907396		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-	Simponi			S	Subcutaneous			Not Reported

Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18291189	EXPEDITED (15-DAY)		OT	IL-LUPIN PHARMACEUTICALS INC.-2020-06142		77 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Hydroxychloroquine Sulfate			S	Oral	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18291990	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELLTRION HEALTHCARE HUNGARY KFT-2020CA025936			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Methotrexate			S	Subcutaneous	Unk, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Bupropion			C	Unknown	Unk		Not Reported

Esomeprazole	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Levothyroxine	C		Unk		Not Reported
Naproxen	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292010	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025826			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	50.0 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydrocortisone Acetate			S	Cutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	1 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Oral	25.0 Milligram, 1 Every 1 Day		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S				Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Orencia	S				Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	1.0 Gram, 2 Every 1 Day		Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S	Unknown	500.0 Milligram		Not Reported
Sulfasalazine	S				Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292018	EXPEDITED (15-DAY)		DE, OT	PK-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-261104		45 YR	Male	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Disease Progression	Meropenem			S	Intravenous (not otherwise specified)	500 Milligram, Tid		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Sun
	Enoxaparin Sodium			S	Subcutaneous	40 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Stat		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 1dose/12hour		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292088	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202009008702			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Condition Aggravated; Dyslipidaemia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Predonine [Prednisolone]			C		Unk		Not Reported
	Sol-Melcort			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			C		Unk		Not Reported
	Prograf			C		Unk		Not Reported
	Bredinin			C		Unk		Not Reported
	Alendronate			C		Unk		Not Reported
	Juvela [Tocopheryl Acetate]			C		Unk		Not Reported
	Nexium [Esomeprazole Magnesium]			C		Unk		Not Reported
	Maintate			C		Unk		Not Reported
	Renivace			C		Unk		Not Reported
	Daiphen			C		Unk		Not Reported
	Pravastatin Sodium			C		Unk		Not Reported
	Brotizolam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292184	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1829547		13 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Febrile Neutropenia; Off Label Use	Doxorubicin			S	Unknown			Teva
	Vincristine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Meropenem			S	Unknown	60 Mg/Kg Daily;		Not Reported
	Teicoplanin			S	Unknown	10 Mg/Kg Daily;		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily; On		Not Reported

	Hydroxychloroquine	S	Oral	First Day 200 Milligram Daily; Administered For 4 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292205	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025890			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous	25 Mg (2 Every 1 Week)		Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Unknown	25 Mg (1 Every 1 Week)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported

	Remicade	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292206	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE HUNGARY KFT-2020CA025880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Ineffective; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil S			S	Oral	400 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Prednisone	C		35 Mg, 1 Every 1 Days		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292235	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025816			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Unknown	40 Milligram, 1 Every 2 Weeks		Not Reported
	Humira			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported

Leflunomide	S	Unknown	20 Milligram, 1 Every 1 Days	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Days	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Days	Not Reported
Methotrexate	S	Oral	20 Milligram, 1 Every 1 Days	Not Reported
Methotrexate	S			Not Reported
Neoral	S	Subcutaneous		Not Reported
Neoral	S	Oral		Not Reported
Orencia	S	Unknown	75 Milligram, 1 Every 1 Months	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Sulfasalazine	S	Oral	500 Milligram, 1 Every 1 Days	Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	5 Milligram	Not Reported
Arava	C	Oral	20 Milligram, 1 Every 1 Days	Not Reported
Cimzia	C	Subcutaneous	200 Milligram, 1 Every 2 Weeks	Not Reported
Risedronate	C	Oral	35 Milligram, 1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292241	EXPEDITED (15-DAY)		HO, LT	CA-CELLTRION INC.-2020CA026955			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Off Label Use; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous drip	1000 Mg		Not Reported
	Rituximab (Unknown)			S				Not Reported
	Procytox			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1 Every 24hrs		Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg, 1 Every 1 Days		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, 1 Every 1 Days		Not Reported
	Apo-Azathioprine			S	Unknown	20 Mg, 1 Every 1 Days		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292259	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075289		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	776 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

Decreased; Urinary Tract Infection	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Desoximetasone		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292282	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026135			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292335	EXPEDITED (15-DAY)		HO, LT, OT	GD-LUPIN PHARMACEUTICALS INC.-2020-06183		8 YR	Male	GRD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Status Epilepticus	Cefdinir		S	Unknown	Unk-For 5 Days	Lupin
	Hydroxychloroquine		S	Oral	200 Milligram-A 5-Day Course	Lupin
	Amoxicillin		S	Unknown	Unk-A 10-Day Course	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292357	EXPEDITED (15-DAY)		OT	CA-ROCHE-2675274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292391	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202009008696			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatocellular Injury; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292516	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025868			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma Of Skin; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Arava			S	Unknown	20 Milligram, Every 1 Day		Not Reported
	Azathioprine Sodium			S	Unknown	150 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Weeks		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	150 Milligram, 3 Every 1 Day		Not Reported
	Methotrexate			S	Oral	1 Every 1 Week		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Neoral			S	Unknown	125 Milligram, 2 Every 1 Days		Not Reported

	Plaquenil	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Days	Not Reported
	Citalopram Hydrobromide	C	Unknown	1 Dosage Form, 1 Every 1 Weeks	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Milligram, Every 1 Day	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Milligram	Not Reported
	Prednisone	C	Unknown	10 Milligram, 1 Every 1 Days	Not Reported
	Prednisone	C	Unknown	10 Milligram, Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292857	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Topical	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Topicort [Desoximetasone]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292874	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077201		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Celebrex			S	Oral	200 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18292980	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026306			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Inflammation; Joint Stiffness; Joint	Rituximab (Unknown)			S	Unknown	1 G		Not Reported
	Rituximab (Unknown)			S	Unknown	1 G		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported

Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Bid	Not Reported
	Kevzara	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, 1/Week	Not Reported
	Orencia	S	Unknown	750 Mg	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293043	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026268			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral;	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Every 1 Weeks		Not Reported

Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Unk, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 1 Months	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Anakinra	C			Not Reported
	Ativan	C			Not Reported
	Benadryl	C			Not Reported
	Darifenacin	C			Not Reported
	Desoximetasone	C	Intramuscular		Not Reported
	Desoximetasone	C	Intra-arterial		Not Reported
	Dilaudid	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Leflunomide	C			Not Reported
	Norflex [Orphenadrine Citrate]	C			Not Reported
	Omnaris	C			Not Reported
	Pantoprazole	C			Not Reported
	Synthroid	C			Not Reported
	Vagifem	C	Vaginal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293153	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA026036			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Sulfasalazine	S	Unknown			Not Reported
Tacrolimus	S	Unknown	5 Dosage Form, Daily		Not Reported
Tacrolimus	S	Unknown	6 Dosage Form, Daily		Not Reported
Prednisone	C	Oral	17 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293183	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-076786		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293220	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Topical	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Cimzia	S	Subcutaneous	Unk		Not Reported
Desoximetasone	S	Oral	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Folic Acid	S	Subcutaneous	1 Milligram		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Topicort [Desoximetasone]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293369	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077248		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Doxycycline			S	Unknown	50 Milligram		Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	Unk Unk, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

Rituximab	S	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Milligram		Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Simponi	C	Subcutaneous	50 Milligram, Qmo		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293385	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026367			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5.0 Milligram, 1 Every 12 Hours		Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293404	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026318			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Methotrexate			C	Unknown	0.8 Ml, 1 Every 1 Weeks		Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293464	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA026308			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown	160.0 Milligram		Not Reported

	Azathioprine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293696	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009441		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Hydroxychloroquine			S	Oral	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Apotex
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin G /00000901/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Penicillin G Procaine			S	Unknown	Unk		Not Reported
	Phenoxymethylpenicillin			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	50 Mg, Qd		Not Reported
	Tylenol /00020001/			C	Unknown	650 Mg, Tid		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293699	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP017918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper;	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported

Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Apo-Diclofenac	S	Topical	Apotex
	Diclofenac Potassium	S	Unknown	Apotex
	Trimethoprim/Sulfamethoxazole	S	Unknown	Apotex
	Hydroxychloroquine	S	Unknown	Apotex
	Methotrexate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold Sodium Thiomalate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Voltarene [Diclofenac Sodium]	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293709	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-261429		38 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Growth Restriction; Premature Delivery	Aspirin			S	Unknown	100 Milligram, Daily		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram Every Other Day		Sun
	Azathioprine			S	Unknown	50 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293949	EXPEDITED (15-DAY)		OT	KR-LUPIN PHARMACEUTICALS INC.-2020-06230		53 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Tid		Lupin
	Azithromycin	S	Unknown	500 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18294072	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA025760			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	5.0 Mg, Qd (1 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18294073	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025716			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	2000.0 Milligram	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50.0 Milligram, 1 Every 1 Week	Not Reported
	Etanercept	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40.0 Gram	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram, 2 Every 1 Day	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram, Cyclical	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	2000.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Methotrexate	S	Other	Unk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Other		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Orencia	S	Subcutaneous	750.0 Milligram, 1 Every 1 Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750.0 Milligram, 1 Every 1 Week	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

	Arava	C	Unknown			Not Reported
	Prednisone	C				Not Reported
	Tofacitinib	C				Not Reported
	Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18294639	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020361094		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Solu Medrol			S		Unk (High-Dose)		Pfizer
	Ascorbic Acid			S		Unk		Not Reported
	Zinc Sulfate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Tocilizumab			S		1 Dose		Not Reported
	Insulin			C		Unk (Infusion)		Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18295393	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017893		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Amlodipine			S	Unknown	Unk		Apotex
	Acetazolamide			S	Unknown	Unk		Not Reported
	Alendronate			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Azathioprine			S				Apotex
	Azathioprine			S				Apotex
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Apotex
	Cyclosporine			S				Apotex

	Enalapril	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S			Apotex
	Metformin	S	Unknown	Unk	Apotex
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Ranitidine	S	Unknown	Unk	Apotex
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Cyclophosphamide	S	Unknown	Unk	Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Unknown	Unk	Not Reported
	Ferrous Fumarate	S	Unknown	Unk	Not Reported
	Insulin	S	Unknown	Unk	Not Reported
	Nutropin	S	Subcutaneous	Unk	Not Reported
	Protropin	S	Intramuscular	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1000 Milligram, Q.M.T.	Not Reported
	Remicade	S			Not Reported
	Remicade	S			Not Reported
	Testosterone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18296018	EXPEDITED (15-DAY)		OT	NVSC2020CA253866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Discomfort;	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Abatacept	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	4 Mg	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18296121	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016444608		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Rheumatrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Actemra			S	Unknown	772 Milligram, Qmo		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qwk		Not Reported
	Celebrex			C	Unknown	100 Mg, Qd		Not Reported
	Depo-Medrol			C	Unknown	Unk		Not Reported

Aleve	C	Unknown	Unk		Not Reported
Robax	C	Unknown	Unk		Not Reported
Prednisone	C		15 Mg, Qd		Not Reported
Naproxen	C		Unk		Not Reported
Tylenol Extra Strength	C		650 Mg, Unk, Prn		Not Reported
Nexium [Esomeprazole Magnesium]	C		40 Mg, Qd		Not Reported
Ventolin [Salbutamol]	C		Unk, Prn		Not Reported
Vitamin B 12 [Vitamin B12 Nos]	C		1000 Mg, Qd		Not Reported
Vit D	C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18296135	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2020M1080307		71 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Hepatitis; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk, Bid Lopinavir/Ritonavir 400mg/100mg Twice Daily		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram Administered 2 Doses 8 Hours Apart		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Mylan
	Aspirin /00002701/			C	Unknown	Unk		Mylan
	Pantoprazole			C	Unknown	Unk		Mylan
	Ramipril			C	Unknown	Unk		Mylan
	Rosuvastatin			C	Unknown	Unk		Mylan
	Warfarin			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18296749	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020182547		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Unknown	Unk	Glaxosmithkline
	Diclofenac	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Phthalylsulfathiazole	S	Oral	1000 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported

Prednisone	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Topicort (Desoximetasone)	S	Cutaneous	Unk	Not Reported
Alendronic Acid	S	Oral	Unk	Not Reported
Paracetamol + Codeine Phosphate	C	Unknown	Unk	Glaxosmithkline
Caffeine Citrate	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol (Paracetamol)	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18297014	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020187020		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline

Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Diclofenac Sodium		S	Unknown	Unk	Glaxosmithkline
	Desoximetasone		S	Oral	Unk	Glaxosmithkline
	Folic Acid		S	Unknown	500 Milligram	Glaxosmithkline
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Apo-Prednisone		S	Unknown	5 Mg	Not Reported
	Arava		S	Oral	Unk	Not Reported
	Cortisone Acetate		S	Unknown	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Fosamax		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Oral	25 Milligram	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine)		S	Oral	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Oral	1 Gram, Once Daily (Qd)	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18297490	EXPEDITED (15-DAY)		DE	IR-PFIZER INC-2020358975		6 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off	Methylprednisolone Acetate			S		Unk		Pfizer
	Methylprednisolone Acetate			S				Pfizer

Label Use; Respiratory Failure	Methylprednisolone Acetate	S			Pfizer
	Azithromycin	S	Unk		Pfizer
	Azithromycin	S			Pfizer
	Azithromycin	S			Pfizer
	Cloxacillin	S	Unk		Not Reported
	Cloxacillin	S			Not Reported
	Cloxacillin	S			Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Cyclophosphamide	S	Unk		Not Reported
	Cyclophosphamide	S			Not Reported
	Cyclophosphamide	S			Not Reported
	Ibuprofen	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18297761	EXPEDITED (15-DAY)		HO, OT	CA-009507513-2009CAN008119		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Singulair			S	Unknown	Dosage Form: Not Specified		Merck
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Amlodipine Besylate			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Bumetanide			S	Unknown	Unk		Not Reported
	Capsaicin			S	Topical	Unk		Not Reported
	Cimetidine			S	Unknown	Dosage Form Not Specified		Not Reported
	Clonidine			S	Unknown	Dosage Form Not Specified		Not Reported
	Diltiazem			S	Unknown	Dosage Form Not Specified		Not Reported

Etanercept	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Ibudilast	S	Unknown	Unk	Not Reported
Ketamine	S	Topical	Unk	Not Reported
Ketamine	S	Oral	Unk	Not Reported
Ketamine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Lidocaine	S	Topical	Unk	Not Reported
Lidocaine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Lithium Carbonate	S	Unknown	Dosage Form Not Specified	Not Reported
Magnesium (Unspecified)	S	Unknown	Unk	Not Reported
Magnesium (Unspecified)	S			Not Reported
Memantine	S	Unknown	Unk	Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Mexiletine	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Acetylcysteine	S	Unknown	Unk, N-Acetylcysteine	Not Reported
Naltrexone Hydrochloride	S	Unknown	4.5 Milligram, 1 Every 24 Hours	Not Reported
Palmidrol	S	Unknown	Unk	Not Reported
Pentoxifylline	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	85.0 Milligram, 1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	95.0 Milligram, 1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	5.0 Milligram	Not Reported
Prednisone	S	Unknown	1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	1 Every 24 Hours	Not Reported
Prednisone	S	Unknown	13.0 Milligram	Not Reported

	Spironolactone	S	Unknown	Unk	Not Reported
	Riboflavin	S	Unknown	Unk, Vitamin B 2	Not Reported
	Riboflavin	S			Not Reported
	Ascorbic Acid	S	Unknown	Unk, Vitamin C	Not Reported
	Calcitonin	C	Unknown	Dosage Form Not Specified	Not Reported
	Ezetrol	C	Unknown	Unk	Merck
	Trazodone Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18298197	EXPEDITED (15-DAY)		OT	NVSC2020BR256384			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	500 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	400 Mg, Bid For Five Days		Not Reported
	Oseltamivir Phosphate			S	Transplacental	75 Mg, Bid		Not Reported
	Heparin			S	Transplacental	40 Iu		Not Reported
	Ceftriaxone			S	Transplacental	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18298599	EXPEDITED (15-DAY)		OT	US-BAYER-2020-193149		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin			S		Unk		Bayer
	Orencia			S		Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Methotrexate	S	Unk	Not Reported
	Mycophenolic Acid	S	Unk	Not Reported
	Rituximab	S	Unk	Not Reported
	Sulfasalazine	S	3000 Mg, Qd	Not Reported
	Tocilizumab	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18298905	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017051248		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Anxiety; Arthropathy; C-Reactive Protein; Chest Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Pain; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Ativan			C		20 Mg, As Needed (Prn)		Not Reported
	Ergocalciferol			C				Not Reported
	Glucosamine			C				Not Reported
	Lansoprazole			C				Not Reported
	Vitamin C			C				Not Reported
	Sulfasalazine			C				Not Reported
	Salmon Oil			C				Not Reported
	Lorazepam			C				Not Reported
	Lansoprazole			C				Not Reported
	Glucosamine			C				Not Reported
	Ergocalciferol			C				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S				Not Reported

Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Urticaria; Wound	Simponi	S	Subcutaneous		Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S			Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Paracetamol	S		10 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Tocilizumab	S			Not Reported
	Tofacitinib Citrate	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Actemra	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Apo-Prednisone	S			Not Reported
	Acetaminophen	S		10 Milligram	Not Reported
	Ascorbic Acid	C			Not Reported
	Salazopyrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299088	EXPEDITED (15-DAY)		DS, LT, OT	NVSC2020CA253972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Not Reported

Antibody Positive; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Alendronate Sodium Trihydrate	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Cortisone Acetate	S	Oral	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	10 Mg	Not Reported
	Xeljanz	S	Unknown	10 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Codeine Phosphate	C	Unknown	Unk	Not Reported

	Caffeine Citrate			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	11490879	NON-EXPEDITED		HO, LT, OT	CA-AMGEN-CANSP2015093585		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion;	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram		Amgen
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Amgen
	Enbrel			S	Subcutaneous	12.5 Milligram, 4 Times/Wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Cyclical		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk		Not Reported

Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Qwk	Not Reported
	Actemra	S	Subcutaneous	161 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk, Qd	Not Reported
	Immune Globulin Intravenous (Human)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S			Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported

Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Orencia	S		250 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	Unk, Qd	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	50 Milligram,	Not Reported
Anakinra	S	Unknown	50 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Triamcinolone	S	Unknown	Unk	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported

Abatacept	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Methotrexate Sodium	S	Unknown	Unk, Qwk	Not Reported
Methotrexate Sodium	S			Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Apo Triamcinolone Aq	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
Triamcinolone Acetonide	S			Not Reported
Triamcinolone Acetonide	S			Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	1 Dosage Form, Qd	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Xeljanz Xr	S	Unknown	11 Milligram, Qd	Not Reported
Folic Acid	C		Unk	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	12375759	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-HQWYE674925FEB03		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Enbrel			S	Subcutaneous	2.5 Milligram, 2 Times/Wk		Pfizer
	Enbrel			S	Subcutaneous	2.5 Milligram, Q2wk		Pfizer
	Enbrel			S	Unknown	2.5 Milligram, One Every Two Weeks		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Prior To 2009		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	25 Milligram		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	12580648	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015383958		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 1x/Day Daily (Qd)		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 1x/Day		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day(Daily, (1 Every 24 Hours))		Not Reported
	Arava			S	Unknown	10 Mg, 1x/Day (Daily)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Anakinra			C	Unknown	Unk		Not Reported

	Kineret	C	Unk		Not Reported
	Kineret	C	Unk		Not Reported
	Kineret	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	12973343	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091580		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Aspirine			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	13121648	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017017327		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Enbrel	S	Unknown	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 To 12.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 To 17.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 To 15 Millgram, Qwk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Codeine	S	Unknown	Unk	Pfizer
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
	Tocilizumab	S	Unknown	680 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ciclosporin	C		150 Mg, 1x/Day	Not Reported
	Rituxan	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	13519416	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038266			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Adalimumab	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Methotrexate	S	Oral	15 Mg, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Folic Acid	C	Oral	2.5 Mg, Unk	Not Reported
Pantoprazole	C	Unknown		Not Reported
Pantoprazole Magnesium	C	Oral	40 Mg, Unk	Not Reported
Tenofovir Disoproxil	C	Unknown		Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Mg, Unk	Not Reported
Xeljanz	C	Unknown		Not Reported
Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	13519757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038156		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Drug Ineffective; Drug Intolerance; Eye Disorder;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Apo-Hydroxyquine	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Intra-arterial	Unk Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	2.5 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	13519886	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037981		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Prednisone			S	Oral	Unk, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Gold	S	Unknown			Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	20 Milligram, Qd		Not Reported
Prednisone	S	Oral	50 Milligram, Qd		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram, Bid		Not Reported
Cimzia	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	13844582	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-067794		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Celecoxib			S	Unknown	200 Milligram, Bid		Not Reported
	Apo Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Toradol	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tramadol	C	Unknown	100 Milligram		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	13929682	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2697		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Product Use Issue; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	3/C G2		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tocilizumab	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	13988289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083265		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Orencia			S	Unknown	40 Milligram, Q2wk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Cyclical		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Methotrexate	C	Oral	10.0 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	15.0 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	2.5 Milligram, Qwk	Not Reported
Methotrexate	C		1 Dosage Form, Qwk	Not Reported
Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
Pantoprazole	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram	Not Reported

Tenofovir Disoproxil Fumarate	C	Unknown	Unk		Not Reported
Pantoprazole Sodium Sesquihydrate	C	Unknown	Unk		Not Reported
Tenofovir Disoproxil	C	Unknown	Unk		Not Reported
Tenofovir	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk		Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd		Not Reported
Pantoprazole Magnesium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	14066264	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017151683		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Reaction; Injection Site Urticaria; Nausea; Rash; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	25 Milligram, Qd		Not Reported
	Simponi			C		Unk		Not Reported
	Atenolol			C	Oral	50 Milligram, Qd		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	300 Milligram,(Q0, 2,6, Week Then Every 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	14235972	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3852		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Esomeprazole Magnesium-Naproxen			C	Unknown			Not Reported
	Naproxen			C	Oral			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	14633601	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-038682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q12h	Not Reported
	Xeljanz	S	Unknown	1 Dosage Form	Not Reported
	Xeljanz	S	Oral	5 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	5 Milligram	Not Reported
	Humira	S	Subcutaneous	50 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	9 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Prednisone	S	Unknown	9 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	9 Milligram	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Infliximab	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	9 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
	Simponi	S	Subcutaneous	Unk, Qmo	Not Reported
	Cortisone	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	600 Milligram, Tid	Not Reported
	Cetirizine Hydrochloride	C	Unknown	10 Milligram, Qd	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	10 Milligram, Qd	Not Reported
	Acetaminophen	C	Unknown	500 Milligram	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	14921463	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043742		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Actemra			S	Oral	4.0 Mg/Kg, Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported

Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi		S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Bid	Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported
	Prevacid		C	Unknown	30 Milligram, Bid	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	14925926	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-009461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times A Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	25 Milligram,Two Every 1 Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk, 5 Years		Not Reported
	Methotrexate Sodium			S	Unknown	200 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported

Arava	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd For 2 Years	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram,1 Every One Day,	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk, For 4 Months	Not Reported
Humira	S	Unknown	15 Milligram, 1 Every 1 Week	Not Reported
Humira	S	Subcutaneous	40 Milligram,1 Every Two Week	Not Reported
Humira	S	Subcutaneous	40 Milligram,Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk For 8 Months	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 6 Months	Not Reported
Apo-Hydroxyquine	S	Oral	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk, For 2 Months	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Week	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram,2 Every One Day	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported

Leflunomide	S	Unknown	20 Milligram, Qwk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Wellbutrin	C	Oral	Unk		Not Reported
Sulfasalazine	C	Unknown	1 Gram, Bid		Not Reported
Bupropion	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	15560134	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018048332		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Dosage Form: Unspecified		Ucb
	Cetirizine Hydrochloride			S		Dosage Form: Unspecified		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Actemra			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Apo-Prednisone			S		5 Mg, Unk		Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Desoximetasone			S	Oral	Dosage Form: Unspecified		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Folic Acid			S		500 Mg, Unk		Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Fosamax			S		Intracorpus Route		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk Milligram		Not Reported
	Hydroxychloroquine			S		Dosage Form: Unspecified		Not Reported

Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Dosage Form: Unspecified	Not Reported
Phthalylsulfathiazole	S		Dosage Form: Unspecified	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous	Not Reported
Sulfasalazine	S	Oral	1 G Two Every 1 Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S			Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S			Not Reported
Cortisone Acetate	S			Not Reported
Cortisone Acetate	S			Not Reported
Diclofenac Sodium	S			Not Reported
Diclofenac Sodium	S			Not Reported
Orencia	S	Subcutaneous		Not Reported
Cortisone Acetate	S		25 Milligram	Not Reported
Cortisone Acetate	S			Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	15565602	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015315			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Infliximab Pfizer (Unknown)	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Lidocaine Hcl	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Cephalexin	C		500 Mg, Tid	Not Reported
	Cephalexin	C		500 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	15565611	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-CELLTRION INC.-2018CA023567			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported

Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Arava	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	15567248	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016181292		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Off Label Use; Osteolysis; Pain; Product Use Issue;	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Dose Range From 20, 15, Than 10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer

Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Unk	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S		Unk, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Remicade	S	Subcutaneous	300 Mg, Every 8 Weeks	Not Reported
	Remicade	S	Subcutaneous	300 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	592 Mg, Every 4 Weeks	Not Reported
	Actemra	S		Unk, Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Weekly	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk, Weekly	Not Reported
	Arava	S	Intravenous (not otherwise specified)	592 Mg, Monthly (Q4wk)	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Desoximetasone	C		Unk	Not Reported
	Infliximab	C	Unknown	300 Mg, Unk	Not Reported
	Infliximab	C	Unknown	300 Milligram, Q8wk	Not Reported
	Infliximab	C	Unknown	Unk	Not Reported
	Cortisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	15936783	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-026580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk Unk, Qd		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Qmo		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

Product Effect Incomplete	Humira	S	Subcutaneous	40 Milligram, Q2wk, Cyclical	Not Reported
	Humira	S	Subcutaneous	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Methotrexate	S	Vaginal	25 Milligram, 4 Times/Wk	Not Reported
	Methotrexate	S	Vaginal	25 Milligram, 4 Times Every 1 Week	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Gigabecquerel	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	40 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk Unk, Prn	Not Reported
	Anakinra	C	Unknown	100 Milligram	Not Reported

Synthroid	C	Unknown	Unk	Not Reported
Lasix [Furosemide]	C	Unknown	40 Milligram, Tid	Not Reported
Enablex [Darifenacin]	C	Oral	Unk Unk, Prn	Not Reported
Ativan	C	Unknown	1 Milligram, Qhs (Qd)	Not Reported
Ativan	C	Unknown	1 Gram, Qd	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Orphenadrine	C	Unknown	1 Dosage Form, Bid	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Dilaudid	C	Unknown	4 Milligram, Q6h	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Dilaudid	C	Unknown	4 Milligram	Not Reported
Furosemide	C	Unknown	40 Milligram, Tid	Not Reported
Cortisone	C	Intramuscular	Unk	Not Reported
Kineret	C	Unknown	100 Milligram	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk Unk, Prn	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk Unk, Bid	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Milligram	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Intravenous (not otherwise specified)	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported

	Morphine Sulphate	C	Unknown	Unk	Not Reported
	Dyclone	C	Unknown	Unk	Not Reported
	Darifenacin Hydrobromide	C	Unknown	Unk Unk, Prn	Not Reported
	Plantago Ovata	C	Unknown	Unk	Not Reported
	Dexmethasone	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
	Darifenacin	C	Unknown	Unk	Not Reported
	Orphenadrine Citrate	C	Unknown	Unk Unk, Q12h	Not Reported
	Orphenadrine Citrate	C	Unknown	1 Dosage Form, Bid	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Intra-articular	Unk	Not Reported
	Desoximetasone	C	Intramuscular	Unk	Not Reported
	Triamcinolone Acetonide	C	Intra-articular	40 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	15965274	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	16343860	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019217974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	2 Gram, Qd		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	16626042	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019031229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort;	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Not Reported

Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Fosamax	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Ucb
	Hydroxychloroquine	S		Unk	Not Reported
	Methotrexate	S	Oral	Unk	Ucb
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Pseudoephedrine Hcl	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Apo-Prednisone	S		Unk	Not Reported
	Arava	S		Unk	Not Reported
	Xeljanz	C			Not Reported
	Methotrexate	S	Intra-arterial		Ucb
	Orencia	S	Subcutaneous		Not Reported
	Simponi	S			Not Reported
	Alendronate Sodium	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Prednisone	S			Not Reported
	Sulfasalazine	S		500 Milligram	Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	16812236	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019136319			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Ibuprofen			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			C	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	17157342	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Cimzia			S	Subcutaneous	Unk		Ucb
	Certolizumab Pegol			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Liver Injury; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound			otherwise specified)		
	Simponi	S	Subcutaneous	Solution	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Ucb
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Sulfasalazine	S		Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Cosentyx	S	Unknown		Not Reported

Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Pseudoephedrine Hcl	S		Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Calcium	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Quetiapine	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Stelara	S			Not Reported
Leflunomide	S			Not Reported
Sarilumab	S			Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous		Not Reported
Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
Apo-Prednisone	S	Intravenous (not otherwise specified)		Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Alendronate Sodium;Alendronic Acid	S			Not Reported
Folic Acid	S		1 Milligram	Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Abatacept	S	Intravenous (not otherwise specified)		Not Reported

	Hydroxychloroquine		S				Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	17159829	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053623		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Blood Cholesterol Increased; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hypersensitivity; Hypertension; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfathalidine			S				Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	Unk, 2x/Day (Bid)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Milligram, Once Daily (Qd)		Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Humira	S	Subcutaneous	40 Milligram, Solution Subcutaneous	Ucb
Fosamax	S			Not Reported
Folic Acid	S			Not Reported
Folic Acid	S		1 Milligram	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Desoximetasone	S	Oral		Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Arava	S	Oral		Not Reported
Apo-Prednisone	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Diclofenac	S		50 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram	Not Reported
Xeljanz	S			Not Reported
Methotrexate Sodium	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Alendronate Sodium	S			Not Reported
Golimumab	S			Not Reported
Hydroxychloroquine	S			Not Reported
Apo-Folic Acid	S			Not Reported
Prednisone	S		40 Milligram	Not Reported

Prednisone	S			Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Prednisone	S			Not Reported
Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Weekly (Qw)	Not Reported
Diclofenac Sodium	S		50 Milligram	Not Reported
Arava	S			Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Remicade	S			Not Reported
Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
Alendronate Sodium;Alendronic Acid	S			Not Reported
Cortisone Acetate	S			Not Reported
Tocilizumab	S			Not Reported
Alendronate	S			Not Reported
Diclofenac Potassium	C			Not Reported
Salazopyrin	C			Not Reported
Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	17422939	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010154		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg. 2 Evevry 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	2 Every One Day		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported

Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	17440627	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016346047		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram (1 Every 24 Hours)		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Milligram		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported

	Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
	Vitamin C	C		Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Alaskan Salmon Oil	C		Unk	Not Reported
	Glucosamine	C		Unk	Not Reported
	Lansoprazole	C		30 Mg, Bid	Not Reported
	Ativan	C		2 Mg, 3x/Day, As Needed	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	17519917	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07767		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown	Unknown		Not Reported
Prednisone	S	Oral			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Winpred	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	17873866	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020021854		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling;	Cimzia			S	Subcutaneous	400 Milligram, Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Cetirizine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported

Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Golimumab	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Once Daily (Qd)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S		40 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, 2x/Day	Not Reported

			(Bid)	
Sulfasalazine	S	Oral	1 Milligram	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		1 Gram, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Milligram	Not Reported
Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S		Unk	Not Reported
Diclofenac Sodium	S			Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Sarilumab	S			Not Reported
Apo-Hydroxyquine	S			Not Reported
Topicort [Desoximetasone]	S	Topical		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
Fosamax	S	Oral		Not Reported
Leflunomide	S			Not Reported
Cortisone Acetate	S		25 Milligram	Not Reported
Remicade	S	Subcutaneous		Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Stelara	S	Subcutaneous		Not Reported
Apo-Prednisone	S		40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Tocilizumab	S			Not Reported
Actemra	S			Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
Alendronic Acid	S			Not Reported
Salazopyrin	C		Unk	Not Reported
Diclofenac	C		50 Milligram	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	17956174	EXPEDITED (15-DAY)		OT	CA-ACCORD-185904			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Methotrexate			S	Oral	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe,Solution Subcutaneous		Not Reported
	Cortisone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral	1 Every 1 Days		Not Reported

Prednisone	S	Unknown		Not Reported
Pseudoephedrine	S	Unknown		Not Reported
Reactine (Cetirizine)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	2 Every 1 Days	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Xeljanz	S	Unknown	2 Every 1 Days	Not Reported
Apo-Hydroxyquine	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Cetirizine	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	1 Every 1 Days	Not Reported
Sulfasalazine	S	Unknown	2 Every 1 Days	Not Reported
Topicort	S	Subcutaneous		Not Reported
Folic Acid	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Topicort	S	Topical		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18050430	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1064486			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Oral	5 Milligram, Bid		Mylan
	Methotrexate /00113802/			S	Oral	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Actemra			S	Unknown	Unk		Mylan
	Sodium Aurothiomalate			S	Unknown	Unk		Mylan
	Gold			S	Unknown	Unk		Mylan
	Arava			S	Unknown	Unk		Mylan
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Mylan
	Orencia			S	Unknown	Unk		Mylan
	Remicade			S	Intravenous (not otherwise specified)	Unk		Mylan
	Enbrel			S	Subcutaneous	Unk		Mylan
	Xeljanz			C	Oral	5 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18232941	EXPEDITED (15-DAY)			CA-PFIZER INC-2020340848		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Naproxen			C		500 Mg, Bid (Twice A Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18251469	EXPEDITED (15-DAY)		DS, LT, OT	CA-GLAXOSMITHKLINE-			Female	CAN

CA2020181277

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Cutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Alendronic Acid			S	Oral	Unk		Not Reported

Cortison	S	Unknown	25 Milligram		Not Reported
Cortison	S	Oral	Unk		Not Reported
Cortison	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Caffeine + Codeine + Paracetamol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18251517	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020181450		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-	Cetirizine Hydrochloride			S	Unknown	10 Mg		Glaxosmithkline
	Chlorhexidine Gluconate			S	Oral	Unk		Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Mg		Glaxosmithkline
	Desoximetasone			S	Cutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Folic Acid			S	Unknown	5 Mg		Glaxosmithkline
	Acetaminophen			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole			S	Unknown	Unk		Glaxosmithkline
	Cetirizine			S	Unknown	10 Mg		Glaxosmithkline

Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased	Periogard	S	Oral	Solution	Glaxosmithkline
	Periogard	S	Unknown	Solution	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Mg Solution For Infusion	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tofacitinib	S	Unknown	10 Mg	Not Reported
	Alendronic Acid	S	Oral	Unk	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Oxycodone + Paracetamol	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Mg	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Mg	Not Reported
	Prednisone	S	Oral	7.5 Mg	Not Reported
	Actemra	S	Unknown	728 Mg	Not Reported
	Actemra	S	Unknown	752 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	3011.2 Weekly	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Once Daily (Qd)	Not Reported

Fosamax	S	Oral	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, Once Daily (Qd)	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Apo-Prednisone	S	Oral	Unk	Not Reported
Sulfathalidine	S	Oral	2000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S	Unknown	500 Unk	Not Reported
Oxycodone With Acetaminophen	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Oxycodone Hydrochloride Controlled Release	S	Unknown	Unk	Not Reported
Chloraprep	S	Topical	Topical Solution	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Topicorte	S	Cutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Glaxosmithkline
Zopiclone	C	Unknown	Unk	Glaxosmithkline
Pantoprazole	C	Unknown	Unk	Glaxosmithkline
Ibuprofen	C	Unknown	Unk	Glaxosmithkline
Paracetamol + Caffeine	C	Unknown	Unk	Glaxosmithkline
Reactine	C	Unknown	Unk	Glaxosmithkline
Pantoloc	C	Unknown	Unk	Not Reported
Marvelon 28	C	Unknown	Unk	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Ethinyloestradiol And Desogestrel	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Atasol (Paracetamol)	C	Unknown	Unk	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18252637	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181423		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Cutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Gram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Reactine [Cetirizine Hydrochloride]			S	Unknown	10 Milligram, Once Daily (Qd)		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Golimumab			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S			Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S	Oral	25 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Oral	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Topicort (Desoximetasone)	S	Cutaneous	Unk	Not Reported
Caffeine + Codeine + Paracetamol	C	Unknown	Unk	Glaxosmithkline

	Leflunomide	C	Unknown	Unk	Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18252640	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Topicort			S	Topical	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	50 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	25 Milligram		Glaxosmithkline
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Subcutaneous	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	10 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Topicort (Desoximetasone)	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18252869	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181736			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	50 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk Mg		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk Mg		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported

Therapeutic Product Effect Decreased	Golimumab	S	Unknown	Unk		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	5 Milligram		Not Reported
	Alendronic Acid Sodium	S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram		Not Reported
	Caffeine + Codeine + Paracetamol	C	Unknown	Unk		Glaxosmithkline
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18253091	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020180812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Topical	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported

Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Sulfasalazine	S	Oral	2 Gram	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18253092	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020181430		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Discomfort; Drug Hypersensitivity; Drug	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline

Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Desoximetasone	S	Subcutaneous	Unk	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Diclofenac	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Paracetamol	S	Unknown	10 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram 2 Times A Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Alendronic Acid	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Topicorte	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported

Actemra	S	Unknown	Unk		Not Reported
Sulfathalidine	S	Oral	500 Milligram		Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	200 Milligram, 2x/Day (Bid)		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Ascorbic Acid	C	Unknown	Unk		Glaxosmithkline
Ergocalciferol	C	Unknown	Unk		Glaxosmithkline
Glucosamine	C	Unknown	Unk		Glaxosmithkline
Lorazepam	C	Unknown	Unk		Glaxosmithkline
Vitamin C	C	Unknown	Unk		Glaxosmithkline
Xeljanz	C	Unknown	Unk		Not Reported
Lansoprazole	C	Unknown	Unk		Not Reported
Salmon Oil	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Ativan	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18253095	EXPEDITED (15-DAY)		LT, OT	CA-GLAXOSMITHKLINE-CA2020181422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Intolerance; Duodenal Ulcer Perforation; Exposure	Cetirizine Hydrochloride			S	Oral	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	50 Milligram		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Cutaneous	Unk		Glaxosmithkline
	Cortisone Acetate			S	Oral	25 Milligram		Glaxosmithkline

During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Gram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Alendronic Acid	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Cortison	S	Oral	25 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Glaxosmithkline
	Colecalciferol	C	Unknown	Unk	Glaxosmithkline

	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	C	Unknown	Unk		Glaxosmithkline
	Lisinopril	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18253707	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020180858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk Milligram		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	15 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	500 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Unknown	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Xeljanz	S	Unknown	10 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Cortison	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram	Not Reported
Hydroxychloroquine Phosphate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	1 Milligram	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Codeine Phosphate + Paracetamol	C	Unknown	Unk Milligram	Glaxosmithkline
Caffeine Citrate	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18253708	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020181448		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride +			S	Unknown	10 Milligram		Glaxosmithkline

Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Pseudoephedrine Hydrochloride				
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Desoximetasone	S	Cutaneous	Unk	Glaxosmithkline
	Desoximetasone	S	Cutaneous	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Topicort	S	Cutaneous	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Hydrocortisone Acetate	S	Cutaneous	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Alendronate	S	Oral	Unk	Not Reported
	Cortison	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported

Actemra	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Caffeine + Codeine + Paracetamol	C	Unknown	Unk	Glaxosmithkline
Leflunomide	C	Unknown	Unk	Not Reported
Atasol (Caffeine Citrate + Codeine Phosphate + Paracetamol)	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18253982	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020181655			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Cutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tofacitinib			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Alendronate Sodium	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Oral	1000 Milligram		Not Reported
Phthalylsulfathiazole	S	Oral	500 Milligram		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Oral	1000 Milligram		Not Reported
Sulfasalazine	S	Oral	500 Milligram		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Paracetamol + Codeine Phosphate	C	Unknown	Unk		Glaxosmithkline
Caffeine Citrate	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18254334	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181396			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Topical	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline

Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Potassium	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Oral	25 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Diclofenac	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	4 Mg Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Sulfasalazine	S	Oral	2 Gram	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Topicorte	S	Subcutaneous	Unk	Not Reported
	Topicorte	S	Topical	Unk	Not Reported

	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S	Unknown	5 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18254560	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181413		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Hydrocortisone			S	Oral	Unk		Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported

Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	1 Dosage Form	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Alendronic Acid	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Caffeine + Codeine + Paracetamol	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18254561	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	50 Milligram		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported

Simponi	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Alendronate Sodium	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18267500	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200907395		37 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Asthenia; Chills; Cough; Discomfort; Dizziness; Drug Ineffective; Eye Movement Disorder; Influenza; Loss Of Consciousness; Mobility Decreased; Nasopharyngitis; Nausea; Pallor; Psoriasis; Rash; Sensory Loss; Tremor; Vertigo; Yellow Skin	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Cosentyx	S	Subcutaneous	Not Reported
	Celebrex	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Voltaren /00372301/	C	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18289306	EXPEDITED (15-DAY)		DS, LT, OT	CA-GLAXOSMITHKLINE-CA2020182503			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		10 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported

Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral		Not Reported
	Tofacitinib	S		10 Milligram	Not Reported
	Xeljanz	S		10 Milligram	Not Reported
	Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Desoximetasone	S	Cutaneous	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Cutaneous		Glaxosmithkline
	Desoximetasone	S	Oral		Glaxosmithkline
	Diclofenac	S			Glaxosmithkline
	Folic Acid	S		1 Milligram	Glaxosmithkline
	Folic Acid	S		5 Milligram	Glaxosmithkline
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Milligram	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S			Glaxosmithkline
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

Sulfasalazine	S		2000 Milligram		Not Reported
Tocilizumab	S	Subcutaneous	Unk		Not Reported
Tocilizumab	S	Subcutaneous			Not Reported
Paracetamol	C				Glaxosmithkline
Caffeine Citrate	C				Not Reported
Codeine Phosphate	C				Glaxosmithkline
Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297478	EXPEDITED (15-DAY)		CA, OT	TW-ADVANZ PHARMA-202009008672			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297657	NON-EXPEDITED			US-ADVANZ PHARMA-202009008699			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Product Formulation Issue	Hydroxychloroquine			S		Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297919	EXPEDITED (15-DAY)		DE, HO	CA-CELLTRION INC.-2020CA026491			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab (Unknown)			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297954	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025916			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297956	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025743			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20.0 Milligram		Not Reported
	Methotrexate			S	Oral	20.0 Milligram		Not Reported
	Methotrexate			S	Oral	20.0 Milligram		Not Reported

Methotrexate	S	Oral	20.0 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20.0 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20.0 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20.0 Milligram	Not Reported
Methotrexate	S	Oral	20.0 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125.0 Milligram	Not Reported
Orencia	S	Subcutaneous	125.0 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3.0 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Xeljanz	C	Unknown	5.0 Milligram, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297957	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025769			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Blood Pressure Systolic Increased; Cataract; Decreased Appetite; Dizziness; Dyspepsia; Heart Rate Decreased; Nausea; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650.0 Milligram		Not Reported
	Atorvastatin			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Oral	50.0 Milligram		Not Reported
	Cymbalta			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Irbesartan			C				Not Reported

Lipitor [Atorvastatin]	C	Unknown			Not Reported
Prednisone	C				Not Reported
Solu-Medrol	C	Intravenous (not otherwise specified)	100.0 Milligram		Not Reported
Tramadol	C	Unknown	As Required		Not Reported
Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297970	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025822			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Form,1 Every 1 Weeks		Not Reported
	Glumetza			S	Unknown	500.0 Milligram, 2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported
Acetaminophen	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Arava	C	Unknown		Not Reported
Asa	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
D-Alpha Tocopherol	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297977	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025764			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown	64.0 Milligram, 1 Every 1 Week		Not Reported
	Actemra			S	Unknown	64.0 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown	200.0 Milligram		Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported

Ciclosporin	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	200.0 Milligram, 1 Every 1 Week	Not Reported
Cimzia	S	Subcutaneous	200.0 Milligram	Not Reported
Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Week	Not Reported
Enbrel	S	Unknown	50.0 Milligram	Not Reported
Gold	S	Unknown		Not Reported
Humira	S	Unknown	400.0 Milligram, 1 Every 1 Week	Not Reported
Humira	S	Subcutaneous	40.0 Milligram	Not Reported
Humira	S	Subcutaneous	40.0 Milligram, 1 Every 1 Week	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300.0 Milligram	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300.0 Milligram, 1 Every 1 Week	Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram	Not Reported
Simponi	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Piroxicam	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297980	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025908			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Rituximab (Unknown)			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram (1 Every 1 Days)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram (1 Every 1 Days)		Not Reported
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram (2 Every 1 Days)		Not Reported
	Prednisone			C		10 Milligram (1 Every 1 Days)		Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18297987	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025782			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported

Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Cimzia Single-Use Pre-Filled Syringe		S	Subcutaneous	200.0 Milligram	Not Reported
	Enbrel		S	Unknown	50.0 Mg	Not Reported
	Hydroxychloroquine		S	Unknown	400.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400.0 Milligram	Not Reported
	Leflunomide		S	Unknown	20.0 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	25.0 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate		S			Not Reported
	Methotrexate		S	Subcutaneous	20.0 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate		S			Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Varenicline Tartrate		S	Oral	1.0 Dosage Form, 1 Every 1 Day	Not Reported
	Acetaminophen		C			Not Reported
	Esomeprazole Magnesium Trihydrate		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported
	Oxycodone Hydrochloride		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Rosuvastatin Calcium		C	Unknown		Not Reported
	Tofacitinib Citrate		C	Unknown		Not Reported
	Valtrex		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298005	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025913			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298006	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025952			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1 Every 24 Hrs		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Day		Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, 2 Every 1 Day		Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298030	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025876			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25.0 Mg, 2/Week (2 Every 1 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298033	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025892			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Amlodipine Besilate			S	Oral	5 Mg, 1 Every 1 Days		Not Reported
	Amlodipine Besilate			S	Oral	5 Mg, 1 Every 1 Days		Not Reported
	Asacol			S	Oral	800 Mg, 3 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Arthritis; Tremor; Vitamin D Deficiency	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, 1 Every 1 Weeks	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Oral	2.5 Mg, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, 1 Every 2 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Omega Allergenic Extracts	C			Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298037	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA025815			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Mg		Not Reported

Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8.0 Mg	Not Reported
	Apo-Leflunomide	S	Unknown	10.0 Mg	Not Reported
	Apo-Leflunomide	S	Unknown	20.0 Mg	Not Reported
	Enbrel	S	Unknown	50.0 Mg, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400.0 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg	Not Reported
	Leflunomide	S	Unknown	10.0 Mg	Not Reported
	Methotrexate	S	Unknown	15.0 Mg	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Unknown	20.0 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Subcutaneous	125.0 Mg, 1 Every 1 Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	1.0 Gram	Not Reported
	Prednisone	C	Unknown	5.0 Mg	Not Reported
	Prednisone	C	Unknown	10.0 Mg	Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298040	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025881			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Zostavax	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298045	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026136			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Off Label Use; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituximab (Unknown)			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, 1 Every 1 Days		Not Reported
	Mycophenolate Mofetil			S	Oral	1 Every 1 Days		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Sodium			S	Unknown	720.0 Milligram, 2 Every 1 Days		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	150.0 Milligram, 1 Every 1 Days		Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298125	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025914			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported

Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	1 Dosage Form, 1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Lyrica	S	Oral	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Milligram, 1 Every 2 Weeks	Not Reported
	Xeljanz	S	Oral	5 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram 2 Every 1 Day	Not Reported
	Xeljanz	S	Oral	5 Milligram 1 Every 2 Weeks	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298132	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025954			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown	100.0 Milligram		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5.0 Milligram, 2 Every 1 Days		Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Bacillus Calmetteguerin Bcg			C	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298159	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025806			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported

Non-Hodgkin'S Lymphoma; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Unevaluable Event	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Oral	500.0 Milligram, 1 Every 1 Days	Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Unknown	5.0 Nanogram, 2 Every 1 Days	Not Reported
	Xeljanz	S			Not Reported
	Xeljanz	S	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S			Not Reported
	Apo-Azathioprine	S	Unknown	100.0 Milligram	Not Reported
	Arava	S	Oral	20.0 Milligram, 1 Every 1 Weeks	Not Reported
	Arava	S	Oral	20.0 Milligram, 1 Every 1 Weeks	Not Reported
	Azathioprine	S	Unknown	100.0 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	50.0 Milligram, 1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous	400.0 Milligram	Not Reported
	Humira	S			Not Reported
	Humira	S	Unknown	40.0 Milligram, 1 Every 2 Weeks	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400.0 Milligram	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Week	Not Reported
	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown	50.0 Milligram	Not Reported

Orencia	S	Unknown	1 Every 1 Months	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400.0 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200.0 Milligram, 2 Every 1 Days	Not Reported
Adalimumab	C	Unknown		Not Reported
Amoxicillin	C	Unknown		Not Reported
Amoxicillin	C	Unknown		Not Reported
Amoxicillin And Clavulanate Potassium [Amoxicillin Sodium;Clavulanate	C	Unknown		Not Reported
Amoxicillin Trihydrate And Clavulanate Potassium	C	Unknown		Not Reported
Amoxil [Amoxicillin]	C	Unknown		Not Reported
Bcg	C	Intravenous (not otherwise specified)		Not Reported
Bcg	C	Intravesical		Not Reported
Gold	C	Unknown		Not Reported
Hydroxychloroquine	C	Subcutaneous	40.0 Milligram	Not Reported
Hydroxychloroquine	C	Unknown	100.0 Milligram	Not Reported
Hydroxychloroquine	C	Unknown	400.0 Milligram	Not Reported
Risedronate	C	Oral	35.0 Milligram, 1 Every 1 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298171	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025824			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Golimumab	S	Unknown		Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Indometacin	C			Not Reported
	Prednisone	C			Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298176	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025922			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 1 Days		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S				Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, 1 Every 1 Days		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Enbrel	S	Unknown	Unk	Not Reported
	Hydroxychloroquine/00072603/	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Weeks	Not Reported
	Plaquenil	S	Oral	400 Milligram, 1 Every 1 Days	Not Reported
	Prednisone	S	Unknown	20 Milligram	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	2 Dosage Forms, 2 Every 1 Days	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	80 Milligram, 1 Every 1 Days	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C		80 Milligram, 1 Every 1 Days	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	5 Milligram, 1 Every 1 Days	Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298178	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025949			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain;	Rituximab (Unknown)			S	Intravenous (not			Not Reported

Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Anakinra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Warfarin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298180	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA025878			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported
	Gold			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			C		200 Mg, 2 Every 1 Days		Not Reported

Leflunomide	C	Unknown	20 Mg, Every 1 Days		Not Reported
Lyrica	C		75 Mg, 1 Every 1 Days		Not Reported
Prednisone	C		5 Mg, 1 Every 1 Days		Not Reported
Tocilizumab	C				Not Reported
Trazodone	C		50 Mg, 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298216	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026280			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Asa			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Milligram		Not Reported
	Xeljanz			S	Oral	5.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298417	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010870		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Movement Disorder; Pain; Tuberculosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Voltaren		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298650	EXPEDITED (15-DAY)		HO, LT	CA-CELLTRION INC.-2020CA026751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S				Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Remicade	S	Unknown			Not Reported
Remicade	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298740	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026296			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Neutropenia; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Treatment Failure; Unevaluable Event; Urinary Tract Infection; Wheelchair User	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Oral	25.0 Milligram		Not Reported
	Methotrexate			S	Oral	25.0 Milligram, 2 Every 1		Not Reported

			Days	
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	15.0 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Oral	15.0 Milligram, 1 Every 1 Days	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Morphine	C	Unknown		Not Reported
Penicillamine	C	Unknown		Not Reported
Tofacitinib	C	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported
Tylenol	C	Unknown		Not Reported
Xeljanz	C	Oral	5.0 Milligram, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298771	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026361			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	1 Every 2 Days	Not Reported
	Methotrexate	S	Unknown	15 Milligram, 1 Every 2 Weeks	Not Reported
	Methotrexate	S	Unknown	20 Milligram, 1 Every 1 Week	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 6 Weeks	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298793	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026289			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab (Unknown)			S	Unknown	1000 Mg, Cyclical		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, 2 Every 1 Weeks		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Weeks		Not Reported
	Etanercept			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Oral	25 Mg,1 Every 1 Weeks		Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	10 Mg, 1 Every 1 Days		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Folic Acid	C				Not Reported
Xeljanz	C	Oral	5 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298801	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026428			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, 1 Every 4 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298827	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia		S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Diclofenac Sodium		S	Unknown	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Folic Acid		S	Unknown	Unk	Not Reported
	Fosamax		S	Oral	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298850	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025933			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	100.0 Milligram		Not Reported
	Actemra			S	Intravenous (not	772.0 Milligram, Monthly		Not Reported

			otherwise specified)		
	Enbrel	S	Subcutaneous	50.0 Milligram, 1/Week	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400.0 Milligram, 1/Week	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400.0 Milligram, 1/Week	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400.0 Milligram, 1/Week	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400.0 Milligram, 1/Week	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, 1/Week	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, 1/Week	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, 1/Week	Not Reported
	Methotrexate	S	Oral	25.0 Milligram, 1/Week	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, 1/Week	Not Reported
	Methotrexate	S	Oral	25.0 Milligram, 1/Week	Not Reported
	Myochrysine	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298869	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026353			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18298956	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA026354			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Use Issue; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Rituximab (Unknown)			S	Subcutaneous	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			S	Unknown	325 Mg		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	325 Mg		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo Hydro			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1 Every 1 Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1 Every 24 Hours		Not Reported
	Apo-Prednisone			S	Unknown	20 Nanogram		Not Reported
	Arava			S	Oral	20 Mg, 1 Every 24 Hours		Not Reported
	Arava			S	Unknown	10 Mg, 1 Every 24 Hours		Not Reported

Arava	S	Unknown	20 Mg, 1 Every 1 Day	Not Reported
Arava	S	Oral	20 Mg	Not Reported
Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
Diphenhydramine Hydrochloride;Paracetamol	S	Unknown		Not Reported
Doxycycline	S	Unknown	100 Mg, 2 Every 1 Days	Not Reported
Doxycycline Hyclate	S	Unknown	100 Mg, 2 Every 1 Day	Not Reported
Enbrel	S	Unknown	40 Mg	Not Reported
Enbrel	S	Unknown	50 Mg, 1 Every 1 Week	Not Reported
Enbrel	S	Unknown	50 Mg, 1 Every 1 Day	Not Reported
Enbrel	S	Unknown	50 Mg	Not Reported
Enbrel	S	Unknown	40 Mg, 1 Every 1 Week	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, 2 Every 1 Day	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 2 Every 1 Day	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	200 Mg 2 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2 Every 1 Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2 Every 1 Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Mg	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	200 Mg, 2 Every 1 Day	Not Reported
Leflunomide	S	Oral	20 Mg, 1 Every 1 Day	Not Reported
Leflunomide	S	Unknown	200 Mg, 1 Every 24 Hours	Not Reported
Leflunomide	S	Unknown	20 Mg, 1 Every 24 Hours	Not Reported
Leflunomide	S	Oral	20 Mg, 1 Every 24 Hours	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Orencia	S	Unknown	200 Mg	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 2 Every 1 Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1000 Mg, 1 Every 1 Day	Not Reported
Sulfasalazine	S	Unknown	1000 Mg, 1 Every 1 Day	Not Reported
Sulfasalazine	S	Oral	2000 Mg	Not Reported
Sulfasalazine	S	Oral	2000 Mg	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg	Not Reported
Sulfasalazine	S	Oral	2000 Mg	Not Reported
Sulfasalazine	S	Oral	2000 Mg	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2 Every 1 Day	Not Reported
Sulfasalazine	S	Oral	500 Mg, 2 Every 1 Day	Not Reported
Tylenol	S	Unknown		Not Reported
Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
Celebrex	C	Oral	200 Mg, 2 Every 1 Day	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Celecoxib	C	Unknown		Not Reported

Codeine	C	Unknown		Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Meloxicam	C			Not Reported
Methotrexate	C	Unknown	25 Dosage Form, 1 Every 1 Week	Not Reported
Methotrexate	C	Subcutaneous	20 Mg, 1 Every 1 Week	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, 1 Every 1 Week	Not Reported
Methotrexate	C	Subcutaneous	Unk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	C	Unknown	Unk Unk, 1/Week	Not Reported
Methotrexate	C	Unknown	25 Mg, 1 Every 1 Weeks	Not Reported
Methotrexate	C	Unknown	25 Mg 1 Every 24 Hours	Not Reported
Methotrexate	C	Unknown	1 Every 1 Week	Not Reported
Synthroid	C	Unknown		Not Reported
Synthroid	C			Not Reported
Tylenol With Codeine	C	Unknown		Not Reported
Tylenol With Codeine No.3	C		Unk	Not Reported
Tylenol With Codeine No.3	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299080	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026319			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Off Label Use; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, 1 Every 1 Day		Not Reported

	Arava	S	Unknown	20 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, 1 Every 1 Week	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, 1 Every 1 Day	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299086	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025934			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Topicort			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Fosamax	S	Unknown		Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299166	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026389			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Product Use Issue; Rash; Rash Pruritic;	Rituximab (Unknown)			S	Unknown	1000 Milligram, 2 Every 1 Day		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, 1 Every 1 Week		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, 1 Every 1 Week		Not Reported
	Myochrysine			S	Subcutaneous	50.0 Milligram, 1 Every 1 Month		Not Reported
	Orencia			S	Unknown	780 Milligram, 1 Every 1 Week		Not Reported

Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Remicade		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Ciclosporin		C	Unknown	150 Milligram, 1 Every 1 Week	Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299219	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025896			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram, Every 1 Days		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, 1 Every 1 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299357	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA025900			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Voltaren [Diclofenac]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299478	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025901			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Form, 1 Every 1 Week		Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral	5.0 Mg, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299502	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-29008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Levothyroxine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299504	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-28875			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Infliximab	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Atorvastatin Calcium	C	Unknown	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299597	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025904			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Topical	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported

Folic Acid	S			Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S			Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydrocortisone Acetate	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299653	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025905			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Arava			S	Unknown	20 Mg, Qd (1 Every 1 Days)		Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	200.0 Mg, Qd (1 Every 1 Days)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg, Qd (1 Every 1 Days)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg, Qd (1 Every 1 Days)	Not Reported
	Methotrexate	S	Unknown	20.0 Mg, 1/Week (1 Every 1 Weeks)	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown		Not Reported
	Advil [Ibuprofen]	C		Unk	Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Ketorolac	C	Unknown		Not Reported
	Leflunomide	C	Unknown	20.0 Mg, 1/Week (1 Every 1 Weeks)	Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5.0 Mg, Bid (2 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299656	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-06276		11 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Oseltamivir Phosphate Capsules			S	Unknown	45 Milligram, Bid		Lupin
	Ceftriaxone			S	Unknown	1 Gram, Bid (Capsule)		Lupin
	Azithromycin Tablets, 250 Mg			S	Unknown	250 Milligram, Qd		Lupin
	Azithromycin Tablets, 250 Mg			S	Unknown	Unk		Lupin

	Hydroxychloroquine Sulfate Tablets		S	Unknown	200 Milligram, Bid	Lupin
	Hydroxychloroquine Sulfate Tablets		S	Unknown	Unk	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299668	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025877			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Rituximab (Unknown)			S	Unknown			Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300.0 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, 1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown	640.0 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640.0 Milligram, 1 Every 1 Months		Not Reported
	Actemra			S	Unknown	640.0 Milligram, 1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown	1 Every 1 Weeks		Not Reported
	Actemra			S	Unknown	640.0 Milligram, 1 Every 4 Weeks		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown	200.0 Milligram, 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Unknown	200.0 Milligram		Not Reported

Certolizumab Pegol	S	Unknown	200.0 Milligram, 1 Every 2 Weeks	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	200.0 Milligram, 1 Every 1 Weeks	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Unknown	200.0 Milligram, 1 Every 1 Weeks	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	200.0 Milligram	Not Reported
Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Weeks	Not Reported
Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Weeks	Not Reported
Enbrel	S	Unknown	50.0 Milligram	Not Reported
Gold	S	Unknown		Not Reported
Humira	S	Subcutaneous	40.0 Milligram, 1 Every 1 Weeks	Not Reported
Humira	S	Subcutaneous	40.0 Milligram	Not Reported
Humira	S	Subcutaneous	400.0 Milligram, 1 Every 1 Weeks	Not Reported
Humira	S	Unknown	400.0 Milligram, 1 Every 1 Weeks	Not Reported
Humira	S	Subcutaneous	1 Every 1 Weeks	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Imuran	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported

	Methotrexate	S	Unknown	20.0 Milligram	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	300.0 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400.0 Milligram	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram, 1 Every 1 Weeks	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram	Not Reported
	Simponi	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500.0 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299717	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075345		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Mouth	Orencia			S	Intravenous (not otherwise specified)	500 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported

Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Anakinra		S	Subcutaneous	100 Milligram, Qd	Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram	Not Reported
	Leflunomide		S	Unknown	20 Milligram	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299844	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA025865			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituximab (Unknown)			S	Unknown	1000 Milligram		Not Reported
	Actemra			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Humira			S	Unknown	40 Milligram, 1 Every 2		Not Reported

				Weeks	
Humira	S				Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	20 Milligram, 1 Every 1 Weeks		Not Reported
Methotrexate	S	Oral	20 Milligram, 1 Every 1 Weeks		Not Reported
Methotrexate	S	Unknown	20 Milligram, 1 Every 1 Weeks		Not Reported
Methotrexate	S				Not Reported
Orencia	S	Subcutaneous	125 Milligram, 1 Every 1 Weeks		Not Reported
Plaquenil	S	Oral			Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Simponi	S	Unknown			Not Reported
Sulfasalazine	S	Oral			Not Reported
Meloxicam	C	Oral	7.5 Milligram		Not Reported
Prednisolone	C				Not Reported
Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299896	EXPEDITED (15-DAY)		CA, HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06295			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cytomegalovirus Infection; Congenital Hearing Disorder; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Haemorrhage	Hydroxychloroquine			S	Transplacental	200 Milligram, Qod		Lupin
	Azathioprine			S	Transplacental	50 Milligram, Qd		Not Reported
	Magnesium Sulfate			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18299987	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06296		38 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection Reactivation; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	200 Milligram, Qod		Lupin
	Azathioprine			S	Unknown	50 Milligram, Qd		Not Reported
	Magnesium Sulphate [Magnesium Sulfate]			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300054	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026037			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20.0 Milligram		Not Reported
	Arava			S	Oral	20.0 Milligram, 1 Every 1 Days		Not Reported
	Celebrex			S	Oral	200.0 Milligram, 2 Every 1 Days		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk (Duration: 560.0)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Oral	500.0 Milligram, 2 Every 1 Days		Not Reported
Xeljanz	S	Oral	5.0 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300066	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026278			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	5.0 Milligram, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300103	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026098			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20.0 Milligram, 1 Every 1 Days		Not Reported

Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Humira	S	Subcutaneous	200.0 Milligram, 2 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Unknown	200.0 Milligram, 2 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	100.0 Milligram	Not Reported
	Ativan	C		Unk	Not Reported
	Benadryl	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Dilaudid	C	Unknown	Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Kadian	C		Unk	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	40.0 Milligram	Not Reported
	Lasix [Furosemide]	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Morphine Sulfate	C	Unknown	Unk	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Unk	Not Reported
	Omnaris	C	Unknown	Unk	Not Reported

Oxyneo	C	Unknown	Unk		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Restasis	C	Unknown	Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Trimethoprim	C	Unknown	Unk		Not Reported
Urispas	C	Unknown	200.0 Milligram		Not Reported
Vagifem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300178	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026342			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Arava			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300348	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5.0 Milligram		Not Reported
	Folic Acid			S	Oral	25.0 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	4 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25.0 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram 1 Every 1 Days		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram		Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Rituxan	S	Intravenous drip	Unk		Not Reported
	Sarilumab	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	1.0 Gram 2 Every 1 Days		Not Reported
	Sulfathalidine	S	Unknown	Unk		Not Reported
	Topicorten	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Unknown	5.0 Miligram 2 Every 1 Days		Not Reported
	Zyrtec-D	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300406	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025885			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Adalimumab	C			Not Reported
	Amoxicillin Trihydrate And Clavulanate Potassium	C		Unk	Not Reported
	Amoxil	C	Unknown		Not Reported
	Bacillus Calmette Guerin Bcg	C			Not Reported
	Clavulanate Potassium	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported
	Leflunomide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300543	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026125			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 1 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Evey 1 Week		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300567	EXPEDITED (15-DAY)		HO, LT, OT	CA-CELLTRION INC.-2020CA026719			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood	Rituximab (Unknown)			S	Intravenous (not	1000.0 Mg		Not Reported

Creatinine Increased; Blood Pressure Decreased; Blood Pressure Fluctuation; Blood Pressure Increased; Body Temperature Decreased; Cataract; Chills; Colitis Microscopic; Cough; Diarrhoea; Ear Pruritus; Fatigue; Headache; Hypertension; Hypotension; Malaise; Nasal Congestion; Nasopharyngitis; Oral Pruritus; Perforated Ulcer; Procedural Pain; Pyrexia; Renal Disorder; Single Functional Kidney; Sleep Disorder; Throat Irritation; Weight Decreased; Weight Increased; White Blood Cell Count Decreased			otherwise specified)			
	Apo-Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Naproxen	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Risedronate Sodium	S	Unknown			Not Reported
	Acetaminophen	C	Oral	650.0 Mg		Not Reported
	Diphenhydramine Hydrochloride	C	Oral	50.0 Mg		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100.0 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300615	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026110			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	2000.0 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride;Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Apo-Diclofenac	S	Topical		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	5.0 Mg	Not Reported
	Arava	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac Potassium	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Diclofenac Sodium;Misoprostol	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50.0 Mg, 1 Every 1 Weeks	Not Reported
	Etanercept	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40.0 Mg	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Misoprostol	S	Unknown		Not Reported
	Naprosyn [Naproxen]	S	Unknown		Not Reported

Naproxen	S	Unknown			Not Reported
Nifedipine	S	Unknown			Not Reported
Orencia	S	Subcutaneous	750.0 Mg, 1 Every 1 Weeks		Not Reported
Prednisone	S	Unknown			Not Reported
Pregabalin	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Winpred	S	Unknown			Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid (2 Every 1 Days)		Not Reported
Tofacitinib	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300669	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-261431			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Foetal Exposure During Pregnancy; Premature Baby	Aspirin			S	Transplacental	100 Milligram, Daily		Sun
	Hydroxychloroquine			S	Transplacental	200 Milligram Every Other Day		Sun
	Azathioprine			S	Transplacental	50 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300677	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025862			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Incomplete	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Oral	25 Mg, 1 Every 1 Week		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300694	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025891			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	20 Milligram, 1 Every 1 Days		Not Reported
	Arava			S	Oral	20 Milligram, 1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Oral	175 Milligram, 1 Every 1 Weeks		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300783	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020364152		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscular Weakness; Pulmonary Fibrosis; Skin Lesion	Methylprednisolone			S	Intravenous (not otherwise specified)	Three Pulses Of Iv Methylprednisolone		Pfizer
	Prednisolone			S		20 Mg		Not Reported
	Prednisolone			S		60 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Mycophenolate			S				Not Reported
	Azathioprine			S				Not Reported
	Dapsone			C		Unk		Not Reported
	Ciprofloxacin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300784	EXPEDITED (15-DAY)		DE, OT	MA-PFIZER INC-2020363718		82 YR	Female	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Off Label Use; Pneumonia; Product Use In Unapproved Indication; Septic Shock	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300881	EXPEDITED (15-DAY)		OT	ES-ACCORD-201319		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Off Label Use	Hydroxychloroquine			S		400 Mg Twice A Day First		Not Reported

				Day Followed By 200 Mg Twice A Day For 10 Days	
	Lopinavir/Ritonavir	S		200mg/50mg Twice A Day	Not Reported
	Teicoplanin	S			Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300889	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026043			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous drip	1000.0 Milligram		Not Reported
	Enbrel			S	Unknown	25.0 Milligram, 2 Every 1 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300.0 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300919	EXPEDITED (15-DAY)		OT	ES-ACCORD-201321		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Off Label Use	Hydroxychloroquine			S		On Day 1		Not Reported
	Lopinavir/Ritonavir			S		200mg/50mg Twice A Day		Not Reported
	Teicoplanin			S				Not Reported
	Azithromycin			S				Not Reported
	Etanercept			C				Not Reported
	Methylprednisolone			C				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301038	EXPEDITED (15-DAY)		OT	CA-ACCORD-202221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C		Not Specified		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301040	EXPEDITED (15-DAY)		OT	CA-ACCORD-202219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301042	EXPEDITED (15-DAY)		OT	CA-ACCORD-202228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate		S	Unknown		Accord
	Hydroxychloroquine		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Apo-Prednisone		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Prednisone		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301057	EXPEDITED (15-DAY)		OT	CA-ACCORD-202220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Not Specified		Accord
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	Not Specified		Not Reported
	Xeljanz			C	Oral			Not Reported
	Lipitor			C	Oral	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301158	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methylprednisolone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Erelzi			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301621	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025917			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab (Unknown)		S	Unknown	Unk	Not Reported
	Rituximab (Unknown)		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cosentyx		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Simponi		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Erythromycin		C	Unknown		Not Reported
	Methotrexate		C	Oral	Unk, 1 Every 1 Week	Not Reported
	Morphine		C	Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301646	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2017207669		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Anxiety; Arthropathy; C-Reactive Protein; Chest Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Acetaminophen			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	10 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Hypersensitivity; Infusion Related Reaction; Joint Swelling; Musculoskeletal Pain; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Urticaria; Wound	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Lansoprazole	C		Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Alendronic Acid	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Glaxosmithkline
	Glucosamine	C	Unknown	Unk	Glaxosmithkline
	Ergocalciferol	C	Unknown	Unk	Glaxosmithkline
	Vitamin C	C	Unknown	Unk	Glaxosmithkline
	Lansoprazole	C	Unknown	Unk	Not Reported
	Ativan	C	Unknown	20 Mg, As Needed (Prn)	Not Reported
	Lorazepam	C		Unk	Not Reported

	Salazopyrin		C	Unknown	Unk	Not Reported
	Salmon Oil		C			Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301685	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025884			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Stomatitis	Rituximab (Unknown)			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram, Every 1 Days		Not Reported
	Methotrexate			S	Oral	4 Dosage Forms, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, 1 Every 1 Months		Not Reported
	Methotrexate			C	Unknown	25 Milligram		Not Reported
	Prednisone			C		24 Milligram, 1 Every 1 Days		Not Reported
	Prednisone			C		25 Milligram, Every 1 Days		Not Reported
	Prednisone			C		25 Milligram, 1 Every 1 Days		Not Reported
	Prednisone			C		23 Milligram, 1 Every 1 Days		Not Reported
	Prednisone			C		24 Milligram, Every 1 Days		Not Reported
	Tylenol			C	Unknown			Not Reported
	Tylenol Arthritis			C		As Required		Not Reported

	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301946	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026133			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Piroxicam			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302068	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025849			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Anakinra	S	Unknown	100 Milligram	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Week	Not Reported
	Etanercept	S	Subcutaneous	1 Every 1 Week	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram, 1 Every 1 Day	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	100 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	9 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302116	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026509			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram, 1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	20.0 Milligram, 1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	20.0 Milligram, 1 Every 1 Week		Not Reported
	Asa			C	Unknown	81.0 Milligram		Not Reported
	Clonazepam			C	Oral	0.5 Milligram		Not Reported
	Desipramine			C	Oral	50.0 Milligram		Not Reported
	Gabapentin			C	Oral	300.0 Milligram		Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral	20.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302149	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06062		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Cobicistat;Darunavir			C	Unknown	800 Milligram		Not Reported
	Irbesartan			C	Unknown	Unk		Not Reported

	Lopinavir/Ritonavir	C	Unknown	Unk		Not Reported
	Tenofovir Alafenamide	C	Unknown	Unk		Not Reported
	Tenofovir Alafenamide	C	Unknown	Unk		Not Reported
	Emtricitabine	C	Unknown	Unk		Not Reported
	Emtricitabine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302150	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06063		57 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Cobicistat;Darunavir			C	Unknown	800 Milligram		Not Reported
	Cobicistat;Darunavir			C				Not Reported
	Raltegravir			C	Unknown	Unk		Not Reported
	Nebivolol			C		Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302157	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06053		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lamivudine			S	Unknown	300 Milligram, Qd		Lupin
	Lamivudine			S				Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Darunavir And Cobicistat			C	Unknown	Unk		Not Reported
	Doxazosin			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302166	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830298		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Amoxicillin Sodium/Clavulanate Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tridural			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302168	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Mycophenolate Mofetil			S	Unknown	2 Gram Daily;		Teva
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr

	Mycophenolate Sodium	S	Unknown		Teva
	Prednisone	S	Unknown		Actavis
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302184	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026507			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg		Not Reported
	Leflunomide			S	Unknown	10.0 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	15.0 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	200.0 Mg, 2 Every 1 Day		Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral	5.0 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302208	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026407			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported

Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen	S	Unknown		Not Reported
	Acetaminophen	S	Unknown	325 Mg	Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	20 Mg, 1 Every 1 Day	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Mg, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Every 12 Hours	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous	2000 Mg	Not Reported
	Codeine	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk, 1 Every 1 Week	Not Reported
	Synthroid	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302222	EXPEDITED (15-DAY)		HO, LT, OT	US-BAYER-2020-194486		88 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Bronchiectasis; Cough; Dyspnoea; Exposure During Pregnancy; General Physical Health Deterioration; Intrauterine Infection; Lung Disorder; Premature Delivery; Productive Cough	Ciprofloxacin			S	Oral	800 Mg, Qd		Bayer
	Cefmetazole Sodium			S	Parenteral	4 G, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qod		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qod		Not Reported
	E Keppra			C		Unk		Not Reported
	Metronidazole			S	Oral	Unk		Not Reported
	Prednisolone			S	Unknown	10 Mg		Not Reported

	Predonine [Prednisolone]	C	Unk	Not Reported
	Tacrolimus	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302272	EXPEDITED (15-DAY)		OT	CA-ACCORD-202128		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolic Acid			S	Unknown	2 Every 1 Days		Accord
	Plaquenil			S	Unknown	1 Every 24 Hours		Not Reported
	Procytox			S	Unknown	1 Every 24 Hours		Not Reported
	Rituximab			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Mycophenolic Acid			S	Oral	1 Every 24 Hours		Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302278	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-202051		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation;	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Accord
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported

Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Chlorhexidine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Oxycodone Hydrochloride/Paracetamol	S	Unknown		Not Reported
	Periogard	S	Buccal		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfamethoxazole/Sulfamethoxazole Sodium	S	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Topicort	S	Cutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Pantoloc	C	Unknown	Tablet (Enteric- Coated)	Not Reported

Atasol	C	Unknown		Not Reported
Codeine Phosphate/Paracetamol	C			Not Reported
Salazopyrin	C	Unknown		Not Reported
Pantoprazole	C	Unknown	Not Specified	Not Reported
Desogestrel/Ethinylestradiol	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Ibuprofen	C	Unknown		Not Reported
Cetirizine	C	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Cetirizine	S	Unknown		Not Reported
Chlorhexidine	S	Topical		Not Reported
Chlorhexidine	S	Oral	Gluconate Oral Rinse	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	Usp	Not Reported
Oxycodone	S	Unknown		Not Reported
Oxycodone	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported

	Methotrexate		S	Oral		Accord
	Methotrexate		S	Oral	1 Every 1 Days	Accord
	Methotrexate		S	Oral	1 Every 1 Weeks	Accord
	Methotrexate		S	Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302335	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026423			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Weeks		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302351	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026162			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20.0 Milligram 1 Every 1 Days		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50.0 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	200.0 Milligram 2 Every 2 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000.0 Milligram	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown		Not Reported
	Celebrex	C	Oral	200.0 Milligram 2 Every 1 Days	Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25.0 Milligram 1 Every 1 Weeks	Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302414	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026386			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	420.0 Milligram		Not Reported
	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40.0 Milligram		Not Reported
	Etanercept			S	Subcutaneous	15.0 Milligram 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram 1 Every 2 Weeks		Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Methotrexate	S	Unknown	15.0 Mg/M2		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302430	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026483			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Overdose; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic;	Rituximab (Unknown)			S	Intravenous drip	1000.0 Milligram, 2 Every 1 Day		Not Reported
	Actemra			S	Unknown	360.0 Milligram, 1 Every 1 Weeks		Not Reported
	Actemra			S				Not Reported
	Actemra			S	Unknown	680.0 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S				Not Reported
	Alendronate			S	Unknown	70.0 Milligram, 1 Every 1 Week		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25.0 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	12.0 Milligram	Not Reported
	Methotrexate	S	Oral	10.0 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 1 Week	Not Reported
	Myochrysine	S	Intramuscular	50.0 Milligram, 1 Every 1 Month	Not Reported
	Orencia	S	Unknown	780.0 Milligram, 1 Every 1 Week	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302529	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025929			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Amoxicillin Trihydrate And Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin	S	Unknown		Not Reported
	Clavulin	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg	Not Reported
	Methotrexate	S	Unknown	20 Mg, 1/Week	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	1500 Mg	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		200 Mg, Bid	Not Reported
	Prednisone	C	Unknown	7.5 Mg, Daily	Not Reported
	Tridural	C			Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302554	EXPEDITED (15-DAY)		HO, LT	CA-CELLTRION INC.-2020CA026697			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Rituximab (Unknown)			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S			Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ilaris	S	Subcutaneous		Not Reported
Ilaris	S			Not Reported
Ilaris	S	Unknown		Not Reported
Ilaris	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302559	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025873			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram (1 Every 1 Days)		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram (1 Every 1 Day)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	1 Df (1 Every 1 Days)		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram (1 Every 1 Days)	Not Reported
	Remicade	S	Unknown		Not Reported
	Risedronate Sodium	S	Unknown	35 Milligram (1 Every 1 Week)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302568	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025858			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk, Frequency: Total		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302571	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA025860			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituximab (Unknown)			S	Unknown	1000 Mg		Not Reported

Decreased	Actemra	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg	Not Reported
	Arava	S	Unknown	20 Mg, Every 1 Days	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, 1 Every 1 Weeks	Not Reported
	Humira	S	Unknown	Cyclical	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg, 1 Every 1 Weeks	Not Reported
	Orencia	S	Subcutaneous	125 Mg, 1 Every 1 Weeks	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Meloxicam	C	Oral	7.5 Mg, As Required	Not Reported
	Meloxicam	C	Oral	7.5 Mg	Not Reported
	Prednisolone	C			Not Reported
	Xeljanz	C	Oral	5 Mg, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302662	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03351		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Pre-Filled Syringe, Solution Subcutaneous		Not Reported
	Cimzia			S	Unknown	Unknown. Solution Subcutaneous		Not Reported

	Cimzia	S	Subcutaneous	Unknown. Single Use Pre-Filled Syringe, Solution Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown. Solution Intravenous	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Plaquenil	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302665	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3572871-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Nerve Injury; Visual Impairment	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302736	EXPEDITED (15-DAY)		OT	NVSC2020BR256386			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Novartis
	Oseltamivir			S	Transplacental	Unk		Not Reported
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302780	EXPEDITED (15-DAY)		OT	KR-LUPIN PHARMACEUTICALS INC.-2020-06169		59 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200-300 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302969	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830294		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]				
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Piroxicam	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18303182	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1081147		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Cerebral Venous Thrombosis; Hypotension; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Azithromycin			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18303193	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1081137		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy	Prednisone			S	Unknown	5 Milligram, Qd		Mylan
	Prednisone			S	Unknown	20 Milligram, Qd Dose Increased		Mylan
	Prednisone			S	Unknown	Dose Increased From 5 To 10 Mg Daily		Mylan
	Prednisone			S	Unknown	5 Milligram, Qd Slow Reduction		Mylan
	Prednisone			S	Oral	1 Milligram/Kilogram, Qd		Mylan
	Prednisone			S				Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S				Mylan

Dexamethasone	S	Oral	10 Milligram	Mylan
Dexamethasone	S	Oral	40 Milligram	Mylan
Azathioprine	S	Unknown	100 Milligram	Mylan
Betamethasone	S	Unknown	Unk	Mylan
Belimumab	S	Unknown	Unk	Mylan
Belimumab	S			Mylan
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	500 Milligram/Kilogram	Mylan
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	1000 Milligram/Kilogram	Mylan
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	400 Milligram/Kilogram	Mylan
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	200 Milligram/Kilogram	Mylan
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	500 Milligram/Kilogram Three Times A Week	Mylan
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	500 Milligram/Kilogram	Mylan
Rituximab	S	Intravenous (not otherwise specified)	500 Milligram/Sq. Meter	Mylan
Rituximab	S			Mylan
Romiplostim	S	Subcutaneous	3 Microgram/Kilogram, Qw	Mylan
Romiplostim	S	Subcutaneous	5 Microgram/Kilogram, Qw Dose Increased	Mylan
Romiplostim	S	Subcutaneous	1.5 Microgram/Kilogram, Qw Slow Reduction	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18303327	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1081148		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Venous Thrombosis; Hydrocephalus;	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Azithromycin			S	Unknown	Unk		Mylan

Intraventricular Haemorrhage; Off Label Use	Estrogen	S	Oral	Pill		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18303477	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	Unk, Q2wk		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18303483	EXPEDITED (15-DAY)		HO, OT	US-BAYER-2020-193538			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Exposure During Pregnancy; Intrauterine Infection; Premature Delivery	Ciproxan 200 Mg			S	Oral	800 Mg, Qd		Bayer
	Cefmetazole			S	Parenteral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qod		Not Reported

Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qod		Not Reported
Metronidazole	S	Oral	1.5 G, Qd		Not Reported
Prednisolone	S	Unknown	10 Mg		Not Reported
Tacrolimus	S	Unknown	Unk		Not Reported
E Keppra	C		Unk		Not Reported
Predonine [Prednisolone]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18304003	EXPEDITED (15-DAY)		DS, OT	CA-ALVOGEN-2020-ALVOGEN-114405		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Atenolol			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Naprosyne			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Palafer			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoloc			S	Oral			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Ascorbic Acid			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Ferrous Fumarate			S	Unknown			Not Reported

Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral	Unk,1 Every 2 Week	Not Reported
Prednisone	C			Not Reported
Celecoxib	C	Oral		Not Reported
Celecoxib	C	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyn	S	Unknown		Not Reported
Methotrexate Sodium	S	Oral	25.0mg Unknown	Not Reported
Methotrexate Sodium	S	Oral	20.0mg Unknown	Not Reported
Pantoprazole Sodium	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral	25.0mg Unknown	Not Reported
Methotrexate Sodium	S	Oral	20.0mg Unknown	Not Reported
Naprosyne	S	Oral		Not Reported

	Pantoprazole Sodium	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	20.0mg Unknown	Not Reported
	Methotrexate Sodium	S	Oral	20.0mg Unknown	Not Reported
	Atenolol	S	Oral		Not Reported
	Folic Acid	S	Unknown	400.0mg Unknown	Not Reported
	Folic Acid	S	Unknown	5.0mg Unknown	Not Reported
	Folic Acid	S	Unknown	5.0mg Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	Unk,1 Every 2 Week	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	25mg,Once Every Two Week	Not Reported
	Methotrexate	S	Oral	25mg,Once Every Two Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18304064	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019229151		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Blood	Cetirizine Hydrochloride			S	Unknown	10 Mg		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline

Cholesterol Increased; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hypersensitivity; Hypertension; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Cetirizine Hydrochloride	S			Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Mg	Glaxosmithkline
	Folic Acid	S	Unknown	5 Mg	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	50 Mg	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Mg	Glaxosmithkline
	Cortisone Acetate	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Mg, Qd	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Unknown	20 Mg	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported

Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Mg	Not Reported
Methotrexate	S	Subcutaneous	25 Mg	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	50 Mg	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Oral	Unk	Not Reported
Alendronic Acid	S	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Glaxosmithkline
Diclofenac Potassium	C	Unknown	50 Mg	Glaxosmithkline
Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18304637	EXPEDITED (15-DAY)		OT	NVSC2020IT257258			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Azithromycin	S	Unknown	500 Mg, Qd For Atleast Three Days		Novartis
	Hydroxychloroquine	S	Oral	200 Mg, Bid (8:00am-8:00pm)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18304675	EXPEDITED (15-DAY)		OT	NVSC2020CA259010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Desoximetasone			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	500 Mg (500 Milligram)		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd (1 Gram, Once Daily (Qd))		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg (40 Milligram)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

	Plaquenil (Hydroxychloroquine)	S	Oral	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18305147	EXPEDITED (15-DAY)		OT	NVSC2020CA254245			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Rash; Rheumatic Fever; Rheumatoid Arthritis;	Cetirizine Hydrochloride			S	Unknown	25 Mg		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	50 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cortisone Acetate			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S				Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	20 Mg		Not Reported

Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	50 Mg	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18305629	DIRECT		HO			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Body Temperature Increased; Chapped Lips; Drug Ineffective; Hepatic Enzyme Increased; Hypersensitivity; Lip Pain; Lip Swelling; Pain Of Skin; Pustule; Rash; Rash; Rash; Rash; Rash Erythematous; Skin Burning Sensation; Skin Exfoliation; White Blood Cell Count Increased	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18306073	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026484			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Rash; Syncope; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Unknown	4 Mg/Kg		Not Reported
	Arava			S	Oral	10 Milligram, 1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, 1 Every 1 Months		Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18306145	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026310			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Rituximab (Unknown)			S	Intravenous (not	1000.0 Milligram		Not Reported

Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation				otherwise specified)		
	Actemra		S	Unknown	200.0 Milligram, 1 Every 1 Months	Not Reported
	Arava		S	Unknown	20.0 Milligram, 1 Every 1 Days	Not Reported
	Enbrel		S	Unknown		Not Reported
	Folic Acid		S	Unknown	1.0 Milligram, 1 Every 1 Days	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200.0 Milligram, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18306180	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026330			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Milligram 1 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram 1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	20.0 Milligram 1 Every 1 Days		Not Reported
	Methotrexate			S	Oral	20.0 Milligram 1 Every 1 Weeks		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rosuvastatin Calcium			C	Oral	20.0 Milligram		Not Reported
	Nitroglycerin			C				Not Reported

Asa	C	Unknown	81.0 Milligram		Not Reported
Clonazepam	C	Oral	0.5 Milligram		Not Reported
Gabapentin	C	Oral	300.0 Milligram		Not Reported
Desipramine	C	Unknown	50.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	10392232	EXPEDITED (15-DAY)		OT	BR-ROCHE-1401352		67 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthritis; Asthenia; Back Pain; Blood Pressure Increased; Blood Urea Increased; Body Height Decreased; Bone Disorder; C-Reactive Protein Increased; Choking; Deafness Unilateral; Dizziness; Drug Hypersensitivity; Ear Infection; Erythema; Fatigue; Finger Deformity; Gait Disturbance; Hand Deformity; Hand Fracture; Headache; Hepatic Steatosis; Hepatic Steatosis; Hepatomegaly; Influenza; Joint Dislocation; Joint Swelling; Mobility Decreased; Muscular Weakness; Nausea; Pain; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Increased; Skin Discolouration; Spinal Disorder; Spinal Pain; Tenosynovitis; Vein	Actemra			S	Intravenous (not otherwise specified)	The Most Recent Infusion Was On 16/Jul2/014. Most Recent Infusion Of Actemra On 02/Jan/2019.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Monthly Dosage: 680mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Cortisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Half Tablet		Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Chondroitin			C				Not Reported
	Atacand			C				Not Reported
	Harpagophytum Procumbens			C				Not Reported
	Aradois			C				Not Reported
	Ultracet			C				Not Reported
	Methotrexate			C				Not Reported

Disorder; Weight Decreased; Weight Decreased	Alenia (Brazil)	C	12/400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	11350033	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-PFIZER INC-2015262877		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Thrombosis; Urticaria	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S				Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S	Unknown	500 Mg		Pfizer
	Sulfasalazine			S				Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S				Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Kineret			S		Unk		Not Reported

Actemra	S	Unknown	Unk	Not Reported
Actemra	S			Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S			Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Ilaris	S	Subcutaneous	Unk, Single (Single Use Vial)	Not Reported
Ilaris	S	Unknown	Unk (Powder For Injection)	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S			Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Mg	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Hydroxychloroquine	S			Not Reported
Oxyquinoline Sulfate	S		Unk	Not Reported
Oxyquinoline Sulfate	S			Not Reported
Xeljanz	C	Oral	Unk, 2x/Day	Not Reported
Xeljanz	C	Unknown	5 Mg (Q2wk)	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Rituximab/Urelumab	C	Unknown	Unk	Not Reported

	Prednisone	C		Unk, 1x/Day	Not Reported
	Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	11515749	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2015293060		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily	Enbrel			S	Subcutaneous	12.5 Mg, Weekly		Unknown
	Enbrel			S	Subcutaneous	25 Mg, Every Two Week		Unknown
	Enbrel			S	Subcutaneous	25 Mg, Unk		Unknown
	Enbrel			S	Subcutaneous	25 Milligram		Unknown
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Day		Unknown
	Enbrel			S	Subcutaneous	25 Mg, Weekly		Unknown
	Enbrel			S	Subcutaneous	12.5 Mg, 4times/Wk		Unknown
	Enbrel			S	Unknown	25 Milligram, Qwk		Unknown
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Unknown
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Unknown
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Unknown
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Unknown
	Enbrel			S	Unknown	25 Milligram		Unknown
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly (1 Every 1 Week)		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))		Pfizer
	Infliximab Hospira			S	Unknown	3 Mg, Weekly		Pfizer
	Infliximab Hospira			S	Intravenous (not	5 Milligram		Pfizer

Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting			otherwise specified)		
	Infliximab Hospira	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Pfizer
	Infliximab Hospira	S		1 Dosage Form, Qwk	Pfizer
	Infliximab Hospira	S	Intravenous (not otherwise specified)	3 Milligram	Pfizer
	Methotrexate Sodium	S		15 Mg/M2, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	Unk Unk, Weekly	Pfizer
	Methotrexate Sodium	S		15 Mg, 2x/Week	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	1 Dosage Form, Qwk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, Q2wk	Pfizer
	Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Pfizer
	Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	1 Dosage Form, Qd	Pfizer
	Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Pfizer
	Triamcinolone	S		Unk	Pfizer
	Triamcinolone	S		Unk	Pfizer
	Infliximab	S	Unknown	3 Mg, Weekly	Pfizer
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Pfizer
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Cyclic	Pfizer

Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Pfizer
Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Pfizer
Infliximab	S	Intravenous (not otherwise specified)	3 Milligram	Pfizer
Triamcinolone Acetonide	S	Intra-articular	Unk	Pfizer
Triamcinolone Acetonide	S	Unknown	Unk	Pfizer
Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Pfizer
Triamcinolone Acetonide	S			Pfizer
Xeljanz Xr	S	Unknown	11 Milligram, Qd	Pfizer
Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1 Every 24 Hour(S))	Not Reported
Hydroxychloroquine	S	Oral	5 Mg/Kg, Daily	Not Reported
Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported
Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported

Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S			Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S))	Not Reported
Anakinra	S	Subcutaneous	Unk, Qd	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	50 Milligram	Not Reported
Anakinra	S	Unknown	50 Milligram, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S))	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S))	Not Reported
Orencia	S	Unknown	250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported

Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1x/Day Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Qwk	Not Reported
Actemra	S	Subcutaneous	161 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported

Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1x/Day	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Gammagard	S			Not Reported
Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	1 Dosage Form, Qd	Not Reported
Gamastan	S	Intramuscular	70 G, Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12146308	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2016130747		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Off Label Use; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Pantoloc	S	Unknown	40 Mg, 1x/Day	Pfizer
	Pantoloc	S	Unknown	40 Mg, 1x/Day	Pfizer
	Enbrel	S	Subcutaneous	Unk	Pfizer
	Etanercept	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Cyclic Every 2 Weeks	Pfizer
	Methotrexate Sodium	S	Oral	25 Milligram, 1/Week	Pfizer
	Methotrexate Sodium	S	Oral	20 Milligram, 1/Week	Pfizer
	Methotrexate Sodium	S	Oral	25 Milligram, 1/Week	Pfizer
	Methotrexate Sodium	S	Oral	25 Milligram, Q2weeks	Pfizer
	Methotrexate Sodium	S	Oral	25.0mg Unknown	Pfizer
	Methotrexate Sodium	S	Oral	20 Milligram, Q2weeks	Pfizer
	Methotrexate Sodium	S	Oral	Unk, Q2weeks	Pfizer
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Cyclic (Once Every 2 Weeks)	Pfizer
	Methotrexate Sodium	S	Oral	25 Milligram, 1/Week	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	25.0mg Unknown	Pfizer
	Methotrexate Sodium	S	Oral	25.0mg Unknown	Pfizer
	Methotrexate Sodium	S	Oral	20.0mg Unknown	Pfizer
	Methotrexate Sodium	S	Unknown	Unk,1 Every 2 Week	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, 1x/Day	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, 1x/Day	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, 1x/Day	Pfizer
	Methotrexate Sodium	S	Oral	25mg,Once Every Two Week	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer

Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
Sulfasalazine	S	Oral	500 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Oral	500 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Oral	1000 Mg, 1x/Day	Pfizer
Sulfasalazine	S	Oral	1000 Mg, 1x/Day	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Atenolol	S	Oral	25 Mg, 1x/Day	Pfizer
Atenolol	S	Oral	20 Mg, 1x/Day	Pfizer
Celecoxib	S	Unknown	Unk	Pfizer
Xeljanz	S	Unknown	Unk	Pfizer
Pantoprazole Sodium Anhydrous	S		40 Mg, 1x/Day	Not Reported
Pantoprazole Sodium Sesquihydrate	S		40 Mg, 1x/Day	Not Reported
Apo-Folic Acid	S		5 Mg, 2x/Week	Not Reported
Apo-Folic Acid	S		5 Mg, 2x/Week	Not Reported
Co Atenolol	S		25 Milligram, Qd	Not Reported
Co Atenolol	S		20 Milligram, Qd	Not Reported
Naprosyn E	S	Oral	100 Mg, 1x/Day	Not Reported
Naprosyn E	S	Oral	500 Mg, 2x/Day	Not Reported
Naprosyn E	S	Oral	500 Mg, 2x/Day	Not Reported
Naprosyn E	S	Oral	1000 Mg, 1x/Day	Not Reported
Naprosyn E	S	Unknown	Unk	Not Reported
Naprosyne	S	Oral	100 Milligram, Qd	Not Reported
Naprosyne	S	Oral	500 Milligram, Qd	Not Reported
Naprosyne	S	Oral	500 Milligram, Bid	Not Reported
Naprosyne	S	Oral	1000 Mg, 1x/Day	Not Reported
Palafer Cf	S	Unknown	Unk, 1x/Day	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported

Plaquenil	S	Unknown	400 Mg, 1x/Day	Not Reported
Plaquenil	S	Unknown	40 Mg, 1x/Day	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Oral	20 Mg, 1x/Day	Not Reported
Arava	S	Oral	20 Mg, 1x/Day	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk, 1x/Day	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S		Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S		Unk	Not Reported
Ascorbic Acid	S	Unknown	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Mg, 2x/Day	Not Reported
Folic Acid	S	Unknown	5 Mg, 2x/Week	Not Reported
Folic Acid	S	Unknown	5 Mg, 2x/Week	Not Reported
Folic Acid	S	Unknown	400.0mg Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Mg, 1x/Day	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	40.0mg Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 2x/Day	Not Reported
Ferrous Fumarate/Folic Acid	S		Unk, 1x/Day	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Unknown	1000 Mg, 1x/Day	Not Reported
Naproxen Sodium	S	Unknown	500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Unknown	100 Mg, 1x/Day	Not Reported
Naproxen Sodium	S	Oral	1000 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S		400 Mg, Weekly	Not Reported
Hydroxychloroquine	S		40 Mg, Weekly	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	S		40 Mg, 1x/Day	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	40 Mg, 1x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C	Oral	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, 1x/Day	Not Reported
Prednisone	C		Unk	Not Reported
Celecoxib	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12440760	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-042673		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Anaphylactic Reaction; Arthralgia; Arthropathy; Blood Glucose Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Lupus-Like Syndrome; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Weight Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Mycophenolate Mofetil Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo Mycophenolate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported

Pregabalin	S	Oral		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Plaquenil S	S	Oral	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Prednisone	S	Urethral	25 Milligram, Qd	Not Reported
Prednisone	S	Unknown	1 Dosage Form	Not Reported
Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
Piroxicam	S	Unknown		Not Reported
Piroxicam	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Levothyroxine	C	Unknown		Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	25 Milligram, Qd	Not Reported
Leflunomide	C	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Mycophenolate Mofetil	S			Not Reported
Mycophenolate Mofetil	S			Not Reported
Mycophenolate Mofetil	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12690990	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1432		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Intramuscular		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Intramuscular		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	4-8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported

Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Calcium	C	Unknown		Not Reported
Lantus	C	Subcutaneous		Not Reported
Lantus	C	Unknown		Not Reported
Lozide	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Naprosyn	C	Unknown	As Necessary	Not Reported
Prednisone	C	Unknown	As Required	Not Reported
Prednisone	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported
Vitamin D	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Asa Arthritis Strength Aspirin	C	Unknown		Not Reported
Asa Arthritis Strength Aspirin	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12696887	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1453		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab Hospira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sulfasalazine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12702886	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016087030		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; Bone Disorder; C-Reactive Protein Abnormal;	Enbrel			S	Unknown	50 Milligram, Qwk		Unknown
	Enbrel			S		Unk		Unknown
	Enbrel			S	Unknown	50 Milligram, Qd		Unknown
	Enbrel			S	Unknown	50 Milligram, Qwk		Unknown

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint Laxity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Increased; Off Label Use; Off Label Use; Osteopenia; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Product Use Issue; Product Use Issue; Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Enbrel	S	Unknown	40milligram, 4 Every 1 Week	Unknown
	Enbrel	S	Unknown	50 Milligram, Qwk	Unknown
	Enbrel	S	Unknown	40 Milligram, Four Every One Week	Unknown
	Enbrel	S	Unknown	50 Milligram, Qwk	Unknown
	Enbrel	S	Unknown	50 Milligram, Qd	Unknown
	Enbrel	S	Unknown	50 Milligram, Qwk	Unknown
	Enbrel	S	Unknown	Unk	Unknown
	Enbrel	S	Unknown	50 Milligram, 4 Every 1 Week	Unknown
	Enbrel	S		Unk	Unknown
	Sulfasalazine	S	Oral	2000 Mg, Unk	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Unk	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	25 Df, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	20 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	2.5 Mg/Ml, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly (4 Every 1 Week)	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly	Pfizer
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S		10 Milligram, Qd	Not Reported

Arava	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Unknown	10 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Unknown	20 Mg	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
Plaquenil	S		200 Mg, Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S		200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Remicade	S	Subcutaneous	5 Mg	Not Reported

Actemra	S	Intravenous (not otherwise specified)	800 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	200 Milligram, Unk	Not Reported
Orencia	S	Unknown	200 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	325 Mg, Unk	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Apo-Hydro	S		Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported

Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
Apo-Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Apo Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Amaryl	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk, Qwk	Not Reported
Tylenol With Codeine No.3	C		Unk, As Needed	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Mg, 2x/Day	Not Reported
Celebrex	C		200 Milligram, Bid	Not Reported
Hydromorphone Hcl	C		Unk	Not Reported
Methotrexate	C	Unknown	Unk Unk, Weekly	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Methotrexate	C	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Glyburide (Micronized)	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Lipitor	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk Unk, Qd	Not Reported

Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)		Not Reported
Xeljanz	C		50 Mg, Bid		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12764963	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076342		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported
	Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Aleve			S	Unknown			Not Reported

Methotrexate	S	Unknown	20 Milligram		Not Reported
Cosentyx	S	Unknown	Unk		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram		Not Reported
Prednisone Teva	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Apo-Naproxen	S	Unknown	Unk		Not Reported
Naproxen Sodium	S	Oral	Unk		Not Reported
Prednisone Acetate	S	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram		Not Reported
Folic Acid	C	Subcutaneous	Unk		Not Reported
Methotrexate	C	Unknown	20 Milligram		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Acetaminophen And Codeine	C	Unknown	Unk		Not Reported
Insulin	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid		Not Reported
Celebrex	C	Unknown	2 Dosage Form, Qd		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12854764	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP012836		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Celecoxib			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Naproxen			S	Oral	Unk		Apotex
	Prednisone			S	Unknown			Not Reported

	Pregabalin	S	Unknown	Unk	Not Reported
	Misoprostol	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Apotex
	Amitriptyline	S	Unknown	Unk (Capsule)	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid (2 Every 1 Day)	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk (Not Specified)	Not Reported
	Enbrel	S	Unknown		Not Reported
	Diclofenac W/Misoprostol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	12911486	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-048399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Mirtazapine			S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13000890	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Apo-Diclofenac			S	Unknown	Unk		Apotex
	Apo-Diclofenac			S				Apotex
	Apo-Diclofenac			S				Apotex
	Apo-Diclofenac			S				Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Tramadol			S	Unknown	Unk		Apotex
	Asa 81			S	Unknown			Not Reported
	Asa 81			S				Not Reported
	Asa 81			S				Not Reported
	Asa 81			S				Not Reported
	Diclofenac Potassium			S	Unknown			Apotex
	Diclofenac Potassium			S				Apotex
	Diclofenac Potassium			S				Apotex
	Diclofenac Potassium			S				Apotex
	Diclofenac Sodium			S	Unknown			Apotex
	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin /00002701/			S	Oral	Unk		Not Reported
	Aspirin /00002701/			S				Not Reported
	Aspirin /00002701/			S				Not Reported
	Aspirin /00002701/			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Naprosyn /00256201/	S	Unknown	Unk	Not Reported
Naprosyn /00256201/	S			Not Reported
Naprosyn /00256201/	S			Not Reported
Naprosyn /00256201/	S			Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S			Not Reported
Plaquenil /00072602/	S			Not Reported
Plaquenil /00072602/	S			Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Voltaren /00372301/	S	Unknown		Not Reported
Voltaren /00372301/	S			Not Reported
Voltaren /00372301/	S			Not Reported
Voltaren /00372301/	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk	Not Reported
Tramadol Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13118364	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELLTRION INC.-2015CA012467			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
Abnormal; Alanine Aminotransferase Increased; Arthralgia;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
Arthritis; Arthropathy; Aspartate	Infliximab Pfizer (Unknown)			S	Oral	Unk		Not Reported

Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypertension; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Pulmonary Fibrosis; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S		Unk	Not Reported
	Etanercept	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S		25 Milligram	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2 Times/Wk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral	600 Mg, Q4h	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Qd	Not Reported
	Ibuprofen	S	Oral	Unk Unk, Qd	Not Reported
	Methotrexate Sodium	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported

Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5mg, 4 Times/Wk, .1096mg, 4 In 1 Years, .1315mg, 4 In 1 Years, 10 Mg, 12mg, 17.5mg, 4 Times/Wk, 1	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram, Qd	Not Reported
	Celebrex	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported

Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S	Oral	60 Milligram, Bid	Not Reported
Otezla	S		Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported

Motrin	S	Oral	Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S		Unk	Not Reported
Orencia	S		Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Benadryl	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous drip	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	8 Milligram	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Mogadon	C	Oral	5 Mg, Unk	Not Reported

Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Uloric	C	Oral	160 Mg, 2x/Day	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Oral	50 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported

Oxycodone Hydrochloride	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Naproxen	C		500 Milligram		Not Reported
Cannabis Sativa	C		Unk		Not Reported
Actonel	C	Oral	35 Milligram, Qwk		Not Reported
Vitamin D 3	C	Oral	2000 International Unit		Not Reported
Risedronate Sodium	C	Oral	35 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Arava	C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13395656	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1003		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Middle Insomnia; Nasopharyngitis; Neutropenia; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Thrombocytopenia; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Apo-Leflunomide	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Advil	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Ketorolac	C	Unknown	As Necessary		Not Reported
Naproxen	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13519755	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038176		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported

Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported

Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Prednisone	S	Unknown	1 Mg, Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	20 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Oral	1 Gram 2 Every 1 Days	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Oral	400 Milligram, Qd	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	15 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported

Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram 2 Every 1 Days	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	40 Milligram, Qd	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	20 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

Salazopyrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Leflunomide	C	Oral	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Atasol [Paracetamol]	C	Unknown	Unk		Not Reported
Ibuprofen	C	Unknown			Not Reported
Lisinopril	C	Unknown			Not Reported
Prednisolone	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown			Not Reported
Diclofenac	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13519919	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038134		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulphate	S	Unknown	400 Milligram		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13520451	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-039843		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported

	Cymbalta	C	Unknown	Unk	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Sumatriptan	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Sumatriptan Succinate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13772085	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Foot Deformity; Hand Deformity; Intentional Product Use Issue; Joint Swelling; Leukopenia; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	400 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Toxicity To Various Agents; Visual Impairment	Gold	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Solu-Medrol	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	13869104	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2472			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Apo Hydroxychloroquine	S	Oral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	14597696	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007109		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine			S	Unknown	Unk		Apotex
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown	Unk		Apotex
	Ciprofloxacin			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Bid		Not Reported

	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	14634808	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	14639973	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	14921371	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043739		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported

Abnormal; Synovitis	Hydroxychloroquine Sulphate		S	Unknown	40 Milligram	Not Reported
	Leflunomide		S	Unknown		Not Reported
	Naproxen Sodium		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Naproxen		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Methotrexate		C	Unknown	20 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		C	Unknown		Not Reported
	Hydroxychloroquine Sulphate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15230305	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2276		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Intolerance; Infection; Product Use Issue; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15235072	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0429		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Folic Acid	C	Oral	6 Days Per Week	Not Reported
	Folic Acid	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Hydroxychloroquine	C	Oral		Not Reported
	Hydroxychloroquine	C	Oral		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Hydroxychloroquine	C	Oral		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15299625	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3794		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Treatment Failure	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported

Apo-Leflunomide	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Hydroxychloroquine [Hydroxychloroquine Sulfat	S	Unknown	Not Reported
Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported

	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	C	Oral	Not Reported
	Plaquenil	C	Subcutaneous	Not Reported
	Plaquenil	C	Subcutaneous	Not Reported
	Arava	C	Oral	Not Reported
	Arava	C	Oral	Not Reported
	Risedronate	C	Oral	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15314701	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2018CA022130			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Off Label Use; Product Use Issue; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Milligram, Qwk		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Enbrel			S		50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	640 Milligram, Qwk	Not Reported
Actemra	S	Unknown	640 Milligram, Qmo	Not Reported
Actemra	S	Unknown	Unk, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	640 Milligram	Not Reported
Arava	S	Oral	Unk Unk, Qwk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S		Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
Humira	S	Unknown	400 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	400 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported

Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Imuran	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram , Qwk (2 Years)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Cyclical	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported

	Orencia	S	Subcutaneous	125 Milligram, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Tocilizumab	S	Unknown	640 Mg, Weekly	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Piroxicam	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15332601	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP019358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

	Folic Acid		C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Plaquenil /00072602/		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15518489	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014037808		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	50 Mg		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qd		Pfizer
	Sulfasalazine			S	Oral	1.5 G, Bid		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Penicillin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil			C		Unk		Not Reported
	Plaquenil			C	Unknown	300 Mg		Not Reported
	Plaquenil			C	Unknown	300 Mg		Not Reported
	Vitamin D [Ergocalciferol]			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Tylenol			C		Unk, As Necessary		Not Reported
	Prednisone			C		10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15560216	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181030392		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S				Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Intracavernous			Not Reported

Fosamax	S	Oral	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Phthalylsulfathiazole	S		Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous drip	Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15568781	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1032		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Intolerance; Hepatitis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Kineret			C	Unknown			Not Reported
	Kineret			C	Unknown			Not Reported
	Kineret			C	Unknown			Not Reported

	Anakinra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15632273	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105425		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	500 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Oral	25 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	4 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	40 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Xeljanz	S	Unknown	5 Milligram 2 Every 1 Day	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported

Stelara	S	Subcutaneous	Unk		Not Reported
Sulfathalidine	S	Unknown	Unk		Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Unk		Not Reported
Topicort [Desoximetasone]	S	Topical	Unk		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram		Not Reported
Salazopyrin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15660079	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA024044			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	25 Milligram		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Not Reported
	Enbrel			S	Subcutaneous	2.5 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Subcutaneous	2.5 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, One Every Two Weeks		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	2.5 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	2.5 Milligram, One Every Two Weeks		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported

Enbrel	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Prior To 2009	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S	Intramuscular	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Anakinra		S	Unknown	Unk			Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
	Leflunomide		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15712568	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587985-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Toradol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	15928734	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2507444-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Humira			S	Subcutaneous			Not Reported

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Enbrel	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Etanercept	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	16073865	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2703788-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Prednisone			S	Oral			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Sulfasalazine	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Codeine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	16189081	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011205		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Apotex
	Naproxen Sodium			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown			Apotex
	Azathioprine			S				Apotex
	Cyclosporine			S	Unknown			Apotex
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Medroxyprogesterone			S	Unknown	Unk		Not Reported

Elavil	S	Unknown	Unk		Apotex
Depo-Provera	S	Unknown			Not Reported
Etanercept	S	Unknown	25 Mg, Q.Wk.		Not Reported
Infliximab	S	Unknown	400 Mg, Total		Not Reported
Methotrexate	S	Unknown			Not Reported
Naprosyn /00256201/	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Anakinra	C	Unknown	Unk		Not Reported
Cyclosporine	C	Unknown	Unk		Not Reported
Depo-Provera	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported
Cyclosporine	C	Unknown	Unk		Not Reported
Kineret	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	16440009	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2019DEP000563		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During	Diclofenac Potassium			S	Unknown	Unk		Assertio Therapeutics
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound; Wound	Cortisone	S	Topical	25 Mg	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk, Weekly	Not Reported
	Folic Acid	S	Oral	1 Mg	Not Reported
	Folic Acid	S	Oral	5 Mg, Unk	Not Reported
	Folic Acid	S	Oral	25 Unk, Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk, Once Ever 24 Hours	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Qd	Not Reported
	Methotrexate	S	Oral	1 G, Bid	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Orencia	S	Subcutaneous	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	1000 Mg, Q12h	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfathalidine	S	Unknown	1000 Mg, Q12h	Not Reported
Sulfathalidine	S	Unknown	500 Mg, Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Other	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Zyrtec-D	S	Unknown	10 Mg, Unk	Not Reported
Atasol /00020001/	C		Unk	Not Reported
Salazopyrin	C		Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	16445047	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016526		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200.0 Mg, Bid (2 Every 1 Days)		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Clavulin /00756801/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20.0 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500.0 Mg, Bid (2 Every 1 Days)		Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Prednisone			C	Unknown	7.5 Mg, Qd (1 Every 1 Day)		Not Reported
	Tridural			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	200.0 Mg, Bid (2 Every 1 Days)		Not Reported
	Plaquenil /00072602/			C				Not Reported

	Tylenol /00020001/			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	16489797	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2052		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Nausea; Oedema; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rituxan			S	Unknown	1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Fosamax	S	Subcutaneous	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported

Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Cetirizine	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Naprosyn	S	Unknown	Not Reported
Naprosyn	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Naprosyn	C	Unknown	Not Reported
Naprosyn	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17194720	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201912002914			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Blood Potassium Decreased; Blood Pressure Fluctuation; Chest Discomfort; Chest X-Ray Abnormal; Dental Caries; Fall; Glaucoma; Joint Swelling; Musculoskeletal Chest Pain; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Osteoarthritis; Pain; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture; Seasonal Allergy; Spinal Osteoarthritis; Therapeutic Response Shortened; Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Unknown	1 Dosage Form, Qd(1 In 1d)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	1 Dosage Form,(1 In 2 Wk), 40mg/0.8ml		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	1 Dosage Form, Weekly, (1 In 1 Wk)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk,Solution For Infusion In Pre-Filled Syringe		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	1 Dosage Form, Weekly,(1 In 1 Wk)		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	1 Dosage Form, Weekly,Citrate Free (1 In 1 Wk),40mg/0.4ml		Not Reported
	Iron			C	Unknown	Unk		Not Reported
	Folic (Folic Acid)			C	Unknown	Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Prilosec			C		Unk		Not Reported
	Zantac			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Flexeril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17215818	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1952857US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actonel	S	Oral	35 Mg, Q Week	Allergan
	Actemra	S	Subcutaneous	Unk Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Df	Not Reported
	Anakinra	S	Subcutaneous	100 Mg	Not Reported
	Anakinra	S	Subcutaneous	100 Mg	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2weeks	Not Reported
	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Oral	20 Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	300 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17563805	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022560		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	600 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	6.0 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17577767	EXPEDITED (15-DAY)		LT, OT	CA-JNJFOC-20200329960			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint	Simponi			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17605620	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333278		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Increased Tendency To Bruise; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Rash Erythematous; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Vaginal			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Gold	S	Unknown			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Apo-Leflunomide	S	Oral	Cyclical		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Leflunomide	S	Oral			Not Reported
Risedronate	S	Unknown			Not Reported
Risedronate	S	Unknown			Not Reported
Risedronate	S	Oral			Not Reported
Risedronate Sodium	S	Oral			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	S	Oral			Not Reported
Xeljanz	S	Oral			Not Reported
Actonel	S	Unknown			Not Reported
Actonel	S	Unknown			Not Reported
Actonel	S	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17605643	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200332801		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Density Abnormal; Bone Disorder; Contraindicated Product Administered; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Indometacin	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Indocid /00003801/	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported

	Xeljanz	C	Oral		Not Reported
	Folic Acid	C	Oral		Not Reported
	Cymbalta	C	Oral		Not Reported
	Cefixime	C			Not Reported
	Dienogest	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17605662	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332777		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Cosentyx	S	Unknown	Not Reported
Esomeprazole Sodium	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Arava	C	Unknown	Not Reported
Lyrica	C	Oral	Not Reported
Acetaminophen	C		Not Reported
Altace	C	Unknown	Not Reported
Asa	C		Not Reported
Codeine	C		Not Reported
D-Alpha Tocopherol	C		Not Reported
Ergocalciferol	C		Not Reported
Folic Acid	C		Not Reported
Rosuvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17605665	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332782		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; No Adverse Event; Rheumatoid Arthritis; Stress	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Vioxx	S	Unknown	Not Reported
	Vioxx	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17605716	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Peripheral Swelling; Rheumatoid Arthritis;	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfadiazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Acetaminophen W/Oxycodone	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Butrans	C	Unknown	Not Reported
	Calcium D Pantothenate	C	Unknown	Not Reported
	Nicotinamide W/Pyridoxine Hydrochlo/02518701/	C	Unknown	Not Reported
	Cosentyx	C	Subcutaneous	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Magnesium Citrate	C	Unknown	Not Reported
	Mavik	C	Unknown	Not Reported
	Mometasone	C	Nasal	Not Reported
	Pariet	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported
	Vitamin B12 /00056201/	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Oral	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17605780	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200331857		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Glumetza			S	Unknown	Tablet (Extendedrelease)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Altace			C	Unknown			Not Reported

	Asa	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	D-Alpha Tocopherol	C	Unknown	Not Reported
	Epacaps /06852001/	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17623464	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340472		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17623535	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340121		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anger; Ankylosing Spondylitis; Anxiety; Arthralgia; Back Pain; Balance Disorder; Blood Pressure Increased; Body Temperature Decreased; Chest Injury; Contusion; Decreased Appetite; Dementia; Drug Hypersensitivity; Drug Ineffective; Dyspepsia; Fall; Fatigue; Feeling Abnormal; Heart Rate Increased; Hypotonia; Inappropriate Schedule Of Product Administration; Influenza Like Illness; Injection Site Pain; Intentional Product Use Issue; Limb Discomfort; Lower Respiratory Tract Congestion; Malaise; Memory Impairment; Musculoskeletal Pain; Nasopharyngitis; Neck Pain; Off Label Use; Pain; Pain In Extremity; Paranoia; Pelvic Pain; Photophobia; Pollakiuria;	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported

Product Prescribing Error; Pyrexia; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Weight Decreased	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Duloxetine Hydrochloride	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported

Apo-Prednisone	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Buprenorphine	C	Unknown	5 Mcg		Not Reported
Celebrex	C	Unknown			Not Reported
Dilaudid	C	Unknown			Not Reported
Ibuprofen	C	Unknown			Not Reported
Lorazepam	C	Unknown			Not Reported
Nabilone	C	Unknown			Not Reported
Nabilone	C	Unknown			Not Reported
Nabilone	C	Unknown			Not Reported
Pantoprazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17631812	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200337568		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Back Pain; Body Temperature Increased; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Ear Pain; Headache; Incorrect Route Of Product Administration; Insomnia; Intentional Product Use Issue; Joint Swelling; Lower Respiratory Tract Infection; Muscle Spasticity; Night Sweats; Off Label Use; Pain; Peripheral Swelling; Pruritus; Rash;	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Topical			Not Reported
	Chlorhexidine			S	Subcutaneous			Not Reported
	Chlorhexidine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Respiratory Disorder; Sinusitis; Urticaria; Vomiting			otherwise specified)	
	Acetaminophen	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Acetaminophen W/Oxycodone	S	Unknown	Not Reported
	Chloraprep	S	Subcutaneous	Not Reported
	Chloraprep	S	Subcutaneous	Not Reported
	Chloraprep	S	Topical	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Periogard	S	Buccal	Not Reported
	Percocet	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Folic Acid	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Abatacept	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Cholecalciferol	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported

Reactine /00884302/	C	Unknown		Not Reported
Tylenol /00020001/	C			Not Reported
Ventolin /00139501/	C			Not Reported
Vitamin C /00008001/	C	Unknown		Not Reported
Zopiclone	C	Unknown		Not Reported
Desogestrel W/Ethinylestradiol	C	Unknown		Not Reported
Ergocalciferol	C			Not Reported
Cetirizine	C	Unknown		Not Reported
D-Alpha Tocopherol	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Fish Oil	C		Nutrasea	Not Reported
Alfacalcidol	C	Unknown		Not Reported
Camellia Sinensis	C	Unknown		Not Reported
Coenzyme Q10	C	Unknown		Not Reported
Pantoloc /01263204/	C			Not Reported
Toprim	C	Unknown		Not Reported
Pantoprazole Sodium	C	Intravenous (not otherwise specified)		Not Reported
Vitamin E /00110501/	C	Unknown		Not Reported
Docosahexaenoic Acid	C			Not Reported
Desoximetasone	C	Subcutaneous		Not Reported
Plaquenil	C			Not Reported
Salbutamol	C			Not Reported
Coenzyme Q10	C			Not Reported
Tea, Green	C			Not Reported
One Alpha	C			Not Reported
Vitamin D /00107901/	C			Not Reported
Omega-3 /01866101/	C			Not Reported
Pantoprazole Sodium Anhydrous	C			Not Reported
Apo-Zopiclone	C			Not Reported
Eicosapentaenoic Acid	C			Not Reported
Zopiclone	C			Not Reported
Nutrasea+D	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17648281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403508		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17672253	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200411530		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Arthritis; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound Infection	Simponi	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Chloroquine Diphosphate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Erythromycin	C	Unknown	Not Reported
	Morphine	C	Topical	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17699990	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428562		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17729389	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436797		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Somnolence; Stress; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

Secukinumab	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Intravenous (not otherwise specified)	Not Reported
Azathioprine	S	Vaginal	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Ciclosporin	S	Oral	Not Reported
Ciclosporin	S	Oral	Not Reported
Ciclosporin	S	Oral	Not Reported
Gold	S	Unknown	Not Reported
Lyrica	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	C	Endocervical	Not Reported
Mefenamic Acid	C	Vaginal	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Tylenol /00020001/	C	Unknown	Not Reported
Dequalinium Chloride	C	Subcutaneous	Not Reported
Dequalinium Chloride	C	Subcutaneous	Not Reported
Advil	C	Unknown	Not Reported
Panadeine Co	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported

	Synthroid	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17761493	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-TEVA-2020-CA-1232500		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion;	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral	100 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Oral	2 Dosage Forms Daily;		Actavis
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	1 Dosage Forms Daily;	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral	6 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral	10 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported

Humira	S	Unknown		Not Reported
Humira	S			Not Reported
Hydroxychloroquine	S	Oral	5 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral	1 Dosage Forms Daily;	Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Unknown	1 Dosage Forms Daily;	Not Reported
Infliximab	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous drip		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Respiratory (inhalation)		Not Reported
Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
Prednisone	S	Oral	6 Milligram Daily;	Not Reported
Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral	1 Dosage Forms Daily;	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S			Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Triamcinolone Hexacetonide	S	Other		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17778044	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505943		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Knee Arthroplasty; Limb Operation; Liver Function Test Abnormal; Lung Disorder; Pain; Pancreatitis; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Shoulder Arthroplasty; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Cefazolin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Depo-Medrol	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

	Naproxen	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C		Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17812685	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517496		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Dyspepsia; Gastrointestinal Infection; Hand Deformity; Hepatic Cirrhosis; Hepatic Fibrosis; Hepatic Steatosis; Hypertension; Infection; Joint Ankylosis; Joint Swelling; Localised	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Soriatane			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Infection; Musculoskeletal Stiffness; Nausea; Osteolysis; Pain; Pruritus; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Skin Injury; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Transaminases Increased; Treatment Failure; Upper Respiratory Tract Infection	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Alendronate	S	Unknown	Not Reported
	Cannabis Sativa Oil	S	Unknown	Not Reported
	Cortisone	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Leucovorin /00566701/	S		Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Vitamin D /00107901/	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

Xeljanz	S		Not Reported
Cimzia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Stelara	C	Subcutaneous	Not Reported
Apremilast	C		Not Reported
Invokana	C		Not Reported
Metformin	C		Not Reported
Perindopril	C		Not Reported
Desoximetasone	C	Unknown	Not Reported
Infliximab	C		Not Reported
Hydroxychloroquine	C		Not Reported
Methotrexate	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Enbrel	C		Not Reported
Xeljanz Xr	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17966075	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK048315			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction;	Gabapentin			S	Oral	100 Milligram, Bid		Glenmark

Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Apo-Gabapentin	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Od	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Od	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Od	Not Reported
	Nortriptyline	S	Unknown	Unk	Not Reported
	Nortriptyline	S	Unknown	Unk	Not Reported
	Nortriptyline	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Months	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Celecoxib	S			Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qw	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Months	Not Reported
	Orencia	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
	Plaquenil /00072603/	S	Unknown	400 Milligram, Od	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Od	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram, Od	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Fentanyl	C	Unknown	Unk	Not Reported

Ferrous Gluconate	C	Unknown	Unk	Not Reported
Fish Oil	C	Unknown	Unk	Not Reported
Nasonex	C	Unknown	Unk	Not Reported
Omega 3-6-9 /01334101/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C	Unknown	Unk	Not Reported
Omega-3 Nos	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hcl	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	17975463	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413069		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Nausea; Off Label Use; Treatment Failure	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	4.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cosentyx			S	Unknown	3.0 Years		Not Reported
	Esomeprazole Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	5.0 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			S	Endocervical			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported

	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Rituximab	S	Endocervical	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18027805	EXPEDITED (15-DAY)		HO	CA-ACCORD-190565		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Minutes		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution, 1 Every 2 Weeks		Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)	1 Every 15 Days		Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days		Not Reported
	Humira	S	Subcutaneous	1 Every 1 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18037973	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-JNJFOC-20200724046		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Adjustment Disorder With Depressed Mood; Adverse Drug Reaction; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Fibromyalgia; Gait Disturbance; General Physical Health	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Stelara			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Zyrtec			S	Oral			Not Reported
	Zyrtec			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported

Deterioration; Glossodynia; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infection; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Range Of Motion Decreased; Joint Swelling; Knee Arthroplasty; Liver Function Test Increased; Maternal Exposure During Pregnancy; Memory Impairment; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Oedema; Off Label Use; Pain; Pain In Extremity; Pemphigus; Pericarditis; Peripheral Swelling; Prescribed Overdose; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative Arthritis; Sleep Disorder; Spinal Fusion Surgery; Spondylitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Noncompliance; Type 2	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Mg/0.8 Ml	Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therpay Duration 11 Monts	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Subcutaneous		Not Reported
	Fosamax	S	Intracavernous		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravesical	Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported

Diabetes Mellitus; Vomiting; Walking Aid User; Weight Decreased; Wheezing; Wound; Wound Infection	Desoximetasone	S	Cutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Oral	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Topicort	S	Topical	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Topicort	S	Cutaneous	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Acetaminophen	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported

Methotrexate Sodium	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Pseudoephedrine	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Cosentyx	S		Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Gold	S	Unknown	Not Reported
Apo Hydroxyquine	C	Unknown	Not Reported

	Salazopyrin	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Atasol	C	Unknown		Not Reported
	Ibuprofen	C			Not Reported
	Prinivil	C	Unknown		Not Reported
	Cholecalciferol	C			Not Reported
	Zyrtec /00884302/	C	Unknown		Not Reported
	Tofacitinib	C			Not Reported
	Erythromycin	C	Unknown		Not Reported
	Morphine	C	Intravenous (not otherwise specified)		Not Reported
	Azathioprine	C			Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18042696	EXPEDITED (15-DAY)		OT	CA-ACCORD-191113		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Methotrexate			S	Intramuscular			Accord
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Methotrexate			S	Oral			Accord
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18051220	EXPEDITED (15-DAY)		OT	CA-ROCHE-2642135		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Remicade	S	Subcutaneous	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Not Reported
Topicort [Desoximetasone]	S	Topical	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18065385	EXPEDITED (15-DAY)		OT	CA-ACCORD-191951		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Hydroxychloroquine	S				Not Reported
	Methotrexate	S				Accord
	Cimzia	S	Subcutaneous			Not Reported
	Actemra	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel	S				Not Reported
	Orencia	S				Not Reported
	Potassium	C				Not Reported
	Hydroxychloroquine	S				Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18092075	EXPEDITED (15-DAY)		OT	CA-ACCORD-193272		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate			S				Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Orencia			S				Not Reported
	Celebrex			C				Not Reported
	Septra			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18092232	EXPEDITED (15-DAY)		OT	CA-ACCORD-193377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Cataract; Crepitations; Deformity; Diarrhoea; Dizziness; Drug	Methotrexate			S				Accord
	Actemra			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Arava			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Gold			S				Not Reported

Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Synovial Cyst; Synovitis; Tenosynovitis; Upper Respiratory Tract Infection; Viral Upper Respiratory Tract Infection	Meloxicam	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S				Not Reported
	Hydroxychloroquine	C				Not Reported
	Depo-Medrol	C		Suspension Intra-Articular, 1 Every 1 Days		Not Reported
	Humira	C		Solution Subcutaneous		Not Reported
	Diclofenac	C				Not Reported
	Methylprednisolone	C	Intramuscular	1 Every 1 Days		Not Reported
	Mobicox	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18119001	EXPEDITED (15-DAY)		OT	CA-ACCORD-194333			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S		Frequency: 1 Every 1 Days		Not Reported
	Sulfasalazine			S		Frequency: 2 Every 1 Days		Not Reported
	Xeljanz			S				Not Reported

	Lyrica	C	Not Reported
	Naproxen	C	Not Reported
	Prednisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18122635	EXPEDITED (15-DAY)		OT	CA-ACCORD-194326		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S		1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Months		Not Reported
	Sulfasalazine			S				Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18179645	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-065823		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Piroxicam			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Pregabalin	S	Oral	Unk, Qd		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Sodium Aurothiomalate	S	Parenteral			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Teva Mycophenolate	S	Unknown			Not Reported
Arava	S	Oral	Unk		Not Reported
Prednisone	S	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18184254	EXPEDITED (15-DAY)		HO, OT	PT-VISTAPHARM, INC.-VER202008-001432		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicella Zoster Virus Infection; Viral Vasculitis	Mycophenolate Mofetil, Usp			S		3000 Mg/Day		Vistapharm
	Prednisolone			S		15 Mg/Day		Vistapharm
	Hydroxychloroquine			S		200 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18184338	EXPEDITED (15-DAY)		HO, LT, OT	CA-CELLTRION INC.-2020CA025566			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Anakinra	S			Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S		Unk	Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris	S			Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported

Plaquenil [Hydroxychloroquine Phosphate]	S		Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S				Not Reported
Remicade	S	Unknown			Not Reported
Remicade	S				Not Reported
Sodium Aurothiomalate	S	Intramuscular			Not Reported
Sodium Aurothiomalate	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S				Not Reported
Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18185215	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025533			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Actemra			S	Intracardiac	8.0 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	40.0 Milligram		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab;Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	1000.0 Milligram	Not Reported
Acetaminophen	C	Unknown		Not Reported
Amitriptyline	C	Unknown		Not Reported
Amitriptyline Hydrochloride	C	Unknown		Not Reported
Arava	C	Unknown		Not Reported
Calcium Carbonate	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Elavil /00002202/	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Imitrex [Sumatriptan]	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported
Plaquenil /00072602/	C	Unknown		Not Reported
Premarin	C	Unknown		Not Reported
Sumatriptan Succinate	C	Unknown		Not Reported
Tenormin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18203859	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200834159		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Colitis; Colitis Ulcerative; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Dry Eye; Feeling Abnormal; Joint Swelling; Metabolic Surgery;	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported

Nausea; Sleep Apnoea Syndrome; Therapeutic Product Effect Decreased; Vitiligo; Vomiting	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Imuran /00001501/	S	Unknown	Not Reported
	Mercaptopurine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Vedolizumab	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18207188	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200834179		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sarilumab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18229266	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200842549		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18253975	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-		43 YR	Female	CAN

CA2020181665

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Oral	5 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Hydrocortisone Acetate			S	Oral	Unk		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Sulfasalazine	S	Oral	2 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Unknown	50 Mg	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	2 Mg	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Cortison	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Apo-Hydroxyquine	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Xeljanz	S	Unknown	10 Mg	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Codeine Phosphate	C	Unknown	Unk	Glaxosmithkline
	Paracetamol	C	Unknown	Unk	Glaxosmithkline
	Atasol (Paracetamol)	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Caffeine Citrate	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18260211	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025812			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1.0 G, 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5.0 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18277598	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020357525		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Diarrhoea; Rheumatoid Arthritis	Methotrexate Sodium			S		15 Mg For Many Years		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg		Not Reported
	Allopurinol			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Arava			C	Unknown	20 Mg, 1x/Day		Not Reported
	Carvedilol			C		Unk		Not Reported
	Colchicine			C		Unk		Not Reported
	Entresto			C		Unk		Not Reported
	Ezetimibe			C		Unk		Not Reported
	Lasix [Furosemide]			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18295947	EXPEDITED (15-DAY)		HO	IL-TEVA-2020-IL-1829617		38 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Myasthenia Gravis; Off Label Use	Hydroxychloroquine			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown	600 Milligram Daily;		Teva
	Prednisone			S	Unknown	25 Milligram Daily;		Not Reported
	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Immune Globulin			C	Intravenous (not otherwise specified)	Initial Dose Unknown		Not Reported
	Pyridostigmine			C	Unknown	Five Times Per Day		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18302771	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026527			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise; Mood Swings; Musculoskeletal Stiffness; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, 1 Every 24 Hours		Not Reported
	Apo-Prednisone			S	Oral	25 Milligram, 1 Every 24 Hours		Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, 1 Every 24 Hours		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, 1 Every 24 Hours		Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	1 Gram, 2 Every 1 Days		Not Reported
	Cymbalta			C	Oral	30 Milligram, 1 Every 24		Not Reported

				Hours		
	Folic Acid	C	Oral	1 Every 1 Weeks		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18302859	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-261514		9 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression	Hydroxychloroquine			S	Oral	6 Milligram/Kilogram, Daily		Sun
	Prednisolone			S	Oral	1 Milligram/Kilogram, Daily		Taro
	Prednisolone			S	Oral	40 Milligram, Daily		Taro
	Prednisolone			S	Oral	Unk (Tapered Off)		Taro
	Adapalene			S	Topical	Unk		Not Reported
	Calcipotriol/Betamethasone Dipropionate			S	Topical	Unk (50 Microg Calcipotriol (As Hydrate)/0.5 Mg Betamethasone Hydrate)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303390	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-CELLTRION INC.-2019CA028688			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Grip	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported

Strength Decreased; Headache; Hypersensitivity; Hypertension; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown		Not Reported
	Xeljanz	S	Unknown	5 Mg, Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Unknown	12.5 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, 1 Every 1 Days	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine	S	Unknown	Unk	Not Reported

Sulfate]				
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac	S	Unknown	50 Mg	Not Reported
Folic Acid	S	Unknown	5 Mg	Not Reported
Fosamax	S	Unknown		Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Oral	25 Mg	Not Reported
Methotrexate	S	Oral	20 Mg, 1 Every 1 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported

	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk, 2 Every 1 Days	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Arava	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303428	EXPEDITED (15-DAY)		DE	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-261711		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemia	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303472	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06174		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Levofloxacin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303505	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026504			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder	Rituximab (Unknown)			S	Intravenous (not	1000 Mg		Not Reported

Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia			otherwise specified)			
	Actemra	S	Intravenous (not otherwise specified)	800 Mg, 1 Every 1 Month		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Ug/Kg		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	500 Mg, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303516	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026505			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303534	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026516			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Rituximab (Unknown)		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Celecoxib		S	Oral	200 Mg, 2 Every 1 Days	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303742	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06266		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	800 Milligram, (Daily For 2 Days)		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, (Daily For 5 Days)		Lupin
	Secukinumab			C	Unknown	300 Milligram (At Weeks 0, 1, 2, 3, 4 Followed By A Maintenance Dose Every 4 Weeks)		Not Reported
	Secukinumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303753	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026350			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303793	EXPEDITED (15-DAY)		HO, OT	CA-ALVOGEN-2020-ALVOGEN-114408		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash;	Atenolol			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Ferrous Fumarate			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Palafer			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Cyto-Matrix Vitamin C	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Naprosyn E	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	C			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Atenolol	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40.0mg Unknown	Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Methotrexate	S	Oral	20.0mg Unknown	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18303981	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1829798		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragm Muscle Weakness; Myopathy	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Initial Doses Were Unspecified		Teva

Toxic; Pneumothorax; Toxicity To Various Agents				And It Was Withheld From Mid 20'S To 40years Of	
	Anakinra	S	Subcutaneous	100 Milligram Daily;	Not Reported
	Hydrocortisone	S	Unknown	20 Milligram Daily; In The Morning	Not Reported
	Hydrocortisone	S	Unknown	10 Milligram Daily; In The Afternoon	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304452	EXPEDITED (15-DAY)		OT	CA-ACCORD-202207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Folic Acid			S	Unknown	1 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Xeljanz			S	Oral	1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304564	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830469		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Drug Ineffective; Panniculitis	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

	Azathioprine	S	Unknown	Not Reported
	Colchicine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304664	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-075803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milliliter, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine		S	Oral	1 Gram, Q12h	Not Reported
	Tocilizumab		S	Unknown	Unk	Not Reported
	Tofacitinib Citrate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304697	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06431		11 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Siltuximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304718	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06432		10 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304741	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06433		11 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304778	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06434		12 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine Sulfate		S	Unknown	Unk	Lupin
	Remdesivir		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304824	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06435		365 DAY	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304899	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06436		8 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Remdesivir			C	Unknown	Unk		Not Reported
	Anakinra			C	Unknown	Unk		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18304996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832135		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown			Teva
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305223	EXPEDITED (15-DAY)		DS, OT	CA-COLGATE PALMOLIVE COMPANY-20200901802			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing;	Periogard Alcohol Free Rinse			S	Buccal			Colgate
	Chlorhexidine Gluconate Unspecified			S	Oral			Colgate
	Chlorhexidine Unspecified			S	Topical	Unk		Colgate
	Chlorhexidine Unspecified			S		Unk		Colgate
	Sulfasalazine			S	Oral	500 Mg		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Cortisone			S	Topical	25 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2912 Mg		Not Reported
	Actemra			S	Intravenous (not	3011.2 Mg		Not Reported

Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)	728 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Pseudoephedrine	S			Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Oxycodone;Paracetamol	S			Not Reported
	Sulfamethoxazole	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S		10 Mg	Not Reported
	Oxycodone	S			Not Reported
	Cetirizine	S		10 Mg	Not Reported
	Sulfamethoxazole And Trimethoprim	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral	7.5 Mg	Not Reported
	Leflunomide	S	Oral		Not Reported
	Diclofenac	S			Not Reported
	Fosamax	S	Oral		Not Reported

Apo-Prednisone	S	Oral			Not Reported
Hydroxychloroquine	S	Oral	400 Mg		Not Reported
Cimzia	S	Subcutaneous			Not Reported
Acetaminophen	S				Not Reported
Oxycodone Terephthalate	S				Not Reported
Topicort [Desoximetasone]	S	Cutaneous			Not Reported
Ibuprofen	C				Not Reported
Tylenol [Paracetamol]	C				Not Reported
Pantoloc [Pantoprazole]	C				Not Reported
Cetirizine	C				Not Reported
Desogestrel And Ethinylestradiol	C				Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C				Not Reported
Pantoprazole	C				Not Reported
Salazopyrin	C				Not Reported
Tylenol With Codeine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305352	EXPEDITED (15-DAY)		OT	AU-GENERIC HEALTH PTY. LTD.-2020-06315		71 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram		Lupin
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Tocilizumab			C	Unknown	400 Milligram (Administered 2 Doses 8 Hours Apart)		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305635	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026425			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	5.0 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	500.0 Mg		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	25.0 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400.0 Mg, 1 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305642	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026563			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			S	Unknown	325.0 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported

Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Apo-Acetaminophen	S	Unknown		Not Reported
	Arava	S	Oral	20.0 Milligram, 1 Every 1 Day	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	40.0 Milligram, 4 Every 1 Week	Not Reported
	Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Week	Not Reported
	Enbrel	S	Unknown	50.0 Milligram, 4 Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Day	Not Reported
	Leflunomide	S	Unknown	200.0 Milligram, 1 Every 1 Day	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000.0 Milligram	Not Reported
	Tylenol	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	C			Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25.0 Milligram, 1 Every 1 Week	Not Reported
	Synthroid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305655	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026531			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Somnolence; Visual Impairment	Rituximab (Unknown)		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown	20.0 Mg, Qd (1 Every 1 Days)	Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown	50.0 Mg, 1/Week (1 Every 1 Weeks)	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown	200.0 Mg, Bid (2 Every 1 Days)	Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tylenol		S	Unknown		Not Reported
	Meloxicam		C	Unknown		Not Reported
	Methotrexate		C	Unknown	Unk, 1/Week (1 Every 1 Weeks)	Not Reported
	Synthroid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305674	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026559			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celecoxib			S	Oral	200 Mg, 2 Every 1 Days		Not Reported

	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
	Orencia	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305677	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026551			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	1 Every 24 Hours		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Every 24 Hours		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Risedronate			S	Unknown	35.0 Milligram, 1 Every 1 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305683	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026265			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	200.0 Milligram		Not Reported

Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram	Not Reported
	Leflunomide	S	Unknown	20.0 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	20.0 Milligram, 1 Every 1 Weeks	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Varenicline Tartrate	S	Oral	1.0 Dosage Form, 1 Every 1 Days	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Oral	6 Every 1 Days	Not Reported
	Esomeprazole Magnesium Trihydrate;Naproxen	C			Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Valacyclovir [Valaciclovir]	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305697	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA026519			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade		S	Unknown		Not Reported
	Prednisone		C	Unknown	2 Mg, 1 Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305698	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026920			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305703	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026617			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram, 1 Every 15 Days		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram, 1 Every 15 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, 1 Every 1 Days		Not Reported

Methotrexate	S	Unknown	25 Milligram, 1 Every 1 Weeks		Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Microgram/Kilogram		Not Reported
Sulfasalazine	S	Unknown	500 Milligram, 2 Every 1 Days		Not Reported
Desoximetasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305710	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026652			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1 Every 24 Days		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	20 Mg, 2 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 G, 1 Every 24 Hours		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown	15 Mg, 2 Every 1 Days		Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305728	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026331			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Urethral	400 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	1 G, 2 Every 1 Day		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305730	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026282			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, 1 Every 1 Days		Not Reported

Cell Count Decreased	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Enbrel		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305741	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026561			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Rituximab (Unknown)			S	Unknown	1000.0 Mg, 2 Every 1 Days		Not Reported
	Actemra			S	Unknown	680.0 Mg		Not Reported
	Actemra			S	Unknown	360.0 Mg, 1 Every 1 Months		Not Reported
	Alendronate			S	Unknown	70.0 Mg, 1 Every 1 Weeks		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25.0 Mg		Not Reported
	Humira			S	Unknown	40.0 Mg		Not Reported
	Methotrexate			S	Unknown	10.0 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	10.0 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	12.0 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Oral	10.0 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Ciclosporin	C		Not Reported
Prednisone	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305747	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026746			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305758	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026550			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Toe Amputation; Victim Of Crime	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2 Every 1 Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Ophthalmic	25 Mg, 1 Every 1 Week		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, 2 Every 1 Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, 2 Every 1 Day		Not Reported

Restasis	C	Unknown	Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305762	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026421			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305768	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026610			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma;	Rituximab (Unknown)			S	Unknown	1000 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, 2 Every 1		Not Reported

Product Dose Omission; Toe Amputation					Days	
	Methotrexate		S	Oral	25 Milligram, 1 Every 1 Weeks	Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Days	Not Reported
	Folic Acid		C			Not Reported
	Prednisone		C	Unknown	5 Milligram, 2 Every 1 Days	Not Reported
	Restasis		C			Not Reported
	Synthroid		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305793	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026473			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Subcutaneous	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	1 Every 1 Weeks		Not Reported
	Gold			S	Unknown	1 Every 1 Days		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral	22.5 Mg, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Parenteral	25.0 Mg, 1 Every 1 Weeks	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unk (Therapy Duration: 486.0)	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk, 1 Every 1 Weeks	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Actemra	C	Unknown		Not Reported
Azathioprine	C	Unknown	Unk, 1 Every 1 Days	Not Reported
Ciclosporin	C	Unknown		Not Reported
Cyclosporine	C	Unknown		Not Reported
D-Penicillamine	C			Not Reported
Minocycline	C	Unknown		Not Reported
Penicillamine	C	Unknown		Not Reported
Phenylbutazone	C			Not Reported
Prednisolone	C		6 Mg, Every 1 Days	Not Reported
Prednisone	C	Unknown	6 Mg, 2 Every 1 Days	Not Reported
Tocilizumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305796	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026180			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Weeks		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	125 Milligram, 1 Every 1 Months		Not Reported
	Penicillamine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, 1 Every 1 Months		Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1		Not Reported

Days

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305807	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06270		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Dobutamine			C	Unknown	Unk		Not Reported
	Epinephrine			C	Unknown	Unk		Not Reported
	Levophed			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305828	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA026188			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Humira			S	Unknown	0.8 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Milligram, 1 Evey 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram		Not Reported
	Leflunomide			S	Unknown	10.0 Milligram, 1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	5.0 Milligram		Not Reported
	Methotrexate			S	Unknown	15.0 Milligram		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Unknown	20.0 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S				Not Reported

Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	1.0 Gram, 2 Every 1 Days	Not Reported
Arava	C	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C	Oral	200.0 Milligram, 2 Every 1 Days	Not Reported
Prednisone	C	Unknown		Not Reported
Simponi	C	Subcutaneous		Not Reported
Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305832	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026913			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S				Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305837	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026650			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Thrombosis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	20 Milligram, 1 Every 1 Day		Not Reported
	Prednisone			S	Unknown	20 Milligram, 1 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Warfarin Sodium			S				Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Warfarin Sodium			S				Not Reported
	Amitriptyline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305852	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026567			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5.0 Mg/Kg		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305876	EXPEDITED (15-DAY)		LT	CA-CELLTRION INC.-2020CA027544			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	(Dosage Form: Solution For Infusion)		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Cannabis Sativa			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Subcutaneous	(Dosage Form: Powder For Solution Subcutaneous)	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10.0 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported

	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown	500.0 Milligram	Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	1 Every 12 Hours	Not Reported
	Xeljanz	S			Not Reported
	Lyrica	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305892	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026498			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown	Unk, 3 Every 1 Days		Not Reported
	Xeljanz			C	Oral	5.0 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305893	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026806			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Coumadin			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine Sodium			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305898	EXPEDITED (15-DAY)		OT	CA-ACCORD-202188			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown	1 Every 1 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305915	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026506			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Overdose; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Rituximab (Unknown)			S	Intravenous drip	2 G, 1 Every 6 Months		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown	200 Mg		Not Reported
	Prednisone			S	Unknown	20 Nanogram		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, 2 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, 2 Every 1 Days		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305917	EXPEDITED (15-DAY)		OT	CA-ACCORD-202190			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305926	EXPEDITED (15-DAY)		OT	CA-ACCORD-202187			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks, Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 6 Weeks, Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C	Unknown	Not Specified		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Bupropion/Bupropion Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305934	EXPEDITED (15-DAY)		OT	CA-ACCORD-202213			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18305990	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026298			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	10 Mg, 1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Mg		Not Reported
	Prednisone			C	Unknown	5 Mg, 1 Every 1 Days		Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306150	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026493			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Milligram, 1 Every 1		Not Reported

				Days	
	Enbrel	S	Unknown	25.0 Milligram, 2 Every 1 Days	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Days	Not Reported
	Leflunomide	S	Unknown	20.0 Milligram, 1 Every 1 Days	Not Reported
	Methotrexate	S	Unknown	20.0 Milligram	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	200.0 Milligram, 2 Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram	Not Reported
	Sulfasalazine	C		1.0 Gram, 2 Every 1 Days	Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306237	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026503			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20.0 Milligram, 1 Every 1 Days		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Milligram, 2 Every 1 Days		Not Reported

Methotrexate	S	Unknown	20.0 Milligram, 1 Every 1 Weeks		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Prednisone	C	Unknown	20.0 Milligram, 1 Every 1 Days		Not Reported
Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306238	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026326			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Qd (1 Every 1 Days)		Not Reported
	Methotrexate			S	Oral	25.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Myochrysine			S	Intramuscular	25.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306253	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026372			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Rituximab (Unknown)			S	Intravenous drip			Not Reported

Administered; Drug Ineffective; Headache; Tremor	Actemra	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	50.0 Milligram, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Oral	2.5 Milligram, 1 Every 1 Day	Not Reported
	Methotrexate	C	Oral	15.0 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	C	Oral	10.0 Milligram, 1 Every 1 Week	Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Oral	40.0 Milligram, 1 Every 1 Day	Not Reported
	Tenofovir Disoproxil	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	300.0 Milligram	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown	7.5 Milligram, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306292	EXPEDITED (15-DAY)		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06248		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Ventricular Tachycardia	Hydroxychloroquine		S	Oral	200 Milligram, Bid	Lupin
	Azithromycin		S	Oral	500 Milligram, Qd	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306296	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20200934785		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Atrovent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Ipratropium Bromide W/Salbutamol Sulfate			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec /00661203/			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306363	EXPEDITED (15-DAY)		DE, LT	CA-CELLTRION INC.-2020CA027420			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Rituximab (Unknown)			S	Unknown			Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported

Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Leflunomida	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine	S	Unknown		Not Reported

Sulfate]					
Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral			Not Reported
Sodium Aurothiomalate	S				Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	2 Every 1 Days		Not Reported
Kineret	C	Unknown			Not Reported
Lyrica	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306504	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026518			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Rituximab (Unknown)			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C		10 Milligram		Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported

	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306511	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026315			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	40.0 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Milligram, 2 Every 1 Days		Not Reported
	Folic Acid			C				Not Reported
	Metformin			C				Not Reported

	Rabeprazole Sodium	C	Oral	20.0 Milligram, 1 Every 1 Days		Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306546	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06314		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Epinephrine			C	Unknown	Unk		Not Reported
	Vasopressin			C	Unknown	Unk		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported
	Dobutamine			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306555	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026281			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306603	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026225			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Rituximab (Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306613	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2681128		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diarrhoea; Infection; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cortisone			C				Not Reported
	Salofalk			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306622	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026642			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500.0 Milligram, 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306630	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026555			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre Filled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Subcutaneous	1 Mg	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Topicort	S	Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306640	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-261730		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Gentamicin			S	Unknown	Unk		Taro
	Ampicillin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Kaletra			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Lmwh			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306655	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026568			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306679	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026266			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Overdose; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	2.0 Gram, 1 Every 6 Months		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	20.0 Nanogram		Not Reported
	Arava			S	Unknown	10.0 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Unknown	200.0 Milligram	Not Reported
	Prednisone	S	Unknown	20.0 Nanogram	Not Reported
	Sulfasalazine	S	Unknown	1000.0 Milligram, 2 Every 1 Days	Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown	500.0 Milligram, 2 Every 1 Days	Not Reported
	Sulfasalazine	S			Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306687	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019240684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Subcutaneous	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306718	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832411		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated	Methotrexate			S	Unknown			Barr

Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate	S	Subcutaneous		Barr
	Leflunomide	S	Oral	20 Milligram Daily;	Barr
	Risedronate Sodium	S	Unknown		Teva
	Risedronate Sodium	S	Unknown		Teva
	Risedronate Sodium	S	Oral		Teva
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306822	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-076349			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia	S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Orencia	S	Subcutaneous		Bristol Myers Squibb
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306859	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026607			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Leflunomide			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Unknown	15 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Endocervical	25 Mg, 1 Every 1 Day		Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Meloxicam	C	Unknown			Not Reported
	Simponi	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306881	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026279			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306897	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026341			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Somnolence; Visual Impairment	Arava	S	Unknown	20.0 Milligram, 1 Every 24 Hours	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000.0 Milligram	Not Reported
	Acetaminophen;Codeine	C			Not Reported
	Meloxicam	C			Not Reported
	Methotrexate	C	Unknown	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306900	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026325			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus;	Rituximab (Unknown)			S	Unknown	1.0 Gram		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	5.0 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown	200.0 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Vomiting	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous	50.0 Milligram, 1 Every 1 Weeks	Not Reported
	Folic Acid	S	Unknown	500.0 Milligram	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400.0 Milligram, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram, 1 Every 1 Days	Not Reported
	Methotrexate	S	Subcutaneous	20.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Oral	25.0 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Methotrexate	S			Not Reported
	Naproxen Sodium	S	Unknown	500.0 Milligram, 2 Every 1 Days	Not Reported
	Orencia	S	Subcutaneous	150.0 Milligram, 1 Every 1 Months	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	50.0 Milligram, 1 Every 1 Months	Not Reported
	Sulfasalazine	S	Unknown	500.0 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306913	EXPEDITED (15-DAY)		HO	BR-ACCORD-202300		66 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Supraventricular Extrasystoles	Hydroxychloroquine	S	Not Reported
	Azithromycin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306919	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026646			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306928	EXPEDITED (15-DAY)		OT	CA-ACCORD-202191		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Disorder; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine	S	Unknown	2 Every 1 Days	Not Reported
	Methotrexate	S	Oral	1 Every 1 Weeks	Accord
	Simponi	S	Unknown	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Visanne	C			Not Reported
	Cefixime/Cefixime Trihydrate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306929	EXPEDITED (15-DAY)		OT	CA-ACCORD-202206		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Frequency: 1 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous	Frequency: 1 Every 1 Weeks		Accord
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Prednisone			C	Oral			Not Reported
	Olopatadine			C	Ophthalmic			Not Reported
	Mavik			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Esomeprazole			C		Frequency: 1 Every 1 Days		Not Reported

	Amlodipine	C				Not Reported
	Folic Acid	C	Oral	Frequency: 1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306960	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026670			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306973	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELLTRION INC.-2020CA026164			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sodium Aurothiomalate	S	Intramuscular			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306978	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026415			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307153	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202009008716			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Hypoaesthesia; Injection Site Pain; Intervertebral Disc Compression; Neck Pain; Neuropathy Peripheral; Post Procedural Complication; Post Procedural Infection; Retinal Injury; Spinal Decompression; Spinal Fusion Surgery; Spinal Operation; Vision Blurred	Hydroxychloroquine			S	Unknown			Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	Unk		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307156	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-078524			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tofacitinib Citrate			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

	Sulfasalazine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307224	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830328		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S				Teva
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2681171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Diabetes Mellitus; Head	Actemra			S	Unknown			Not Reported

Titubation; Ill-Defined Disorder; Liver Injury; Neuralgia; Rheumatoid Arthritis; Traumatic Lung Injury; Tremor	Methotrexate Sodium		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307748	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-076383		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram 1 Every 1 Week		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Erelzi [Etanercept Szzs]			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram. 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Tofacitinib		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, 1 Every 2 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830650		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown			Teva
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Esomeprazole Sodium			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S	Subcutaneous			Not Reported
	Nicotinamide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Thiamine Hydrochloride			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307956	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR186983		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Movement Disorder; Pain; Tuberculosis	Voltaren (Diclofenac Diethylammonium Salt)			S				Glaxosmithkline
	Folic Acid			S		Unk		Glaxosmithkline
	Ibuprofen			S		Unk		Glaxosmithkline
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18308002	EXPEDITED (15-DAY)		OT	NVSC2020CA253939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Asthenia; Blood Cholesterol Increased; Bursitis; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Fatigue; General Physical Health Deterioration; Glossodynia; Hand	Diclofenac			S	Unknown	50 Mg		Novartis
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported

Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Inflammation; Infusion Related Reaction; Intentional Product Use Issue; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Maternal Exposure During Pregnancy; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Pemphigus; Pericarditis; Peripheral Swelling; Peripheral Venous Disease; Product Use Issue; Rash	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S			Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg	Not Reported
	Hydroxychloroquine	S	Unknown	400 Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg	Not Reported
	Sulfasalazine	S	Oral	2 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18308007	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1829859		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use;	Hydroxychloroquine			S	Oral	800 Milligram Daily; On Day 1		Teva

Torsade De Pointes	Hydroxychloroquine	S	Oral	400 Milligram Daily; For 4 Days	Teva
	Azithromycin	S	Oral	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18308218	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-076348		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	7.5 Milligram		Not Reported
	Tridural			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18308470	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200932299		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Simponi	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Xeljanz	S	Unknown	1 Dosage Form	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Infliximab	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported

	Cetirizine Hydrochloride	C	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Paracetamol	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18308556	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020368271		25 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Chest Discomfort; Cutaneous T-Cell Lymphoma; Drug Ineffective; Latent Tuberculosis; Off Label Use; Pain; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Tenosynovitis	Methotrexate Sodium			S	Subcutaneous	20 Mg 1 Every 1 Week		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Pfizer
	Cimzia			S	Unknown	200 Mg 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg 1 Every 1 Days		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg 2 Every 1 Days		Not Reported
	Calcium Carbonate			C				Not Reported
	Folic Acid			C				Not Reported
	Omega-3 Nos			C				Not Reported
	Vitamin D3			C	Oral	1000 Iu 1 Every 1 Days		Not Reported
	Vitamin D3			C		2000 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18308767	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1829880		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	800 Milligram Daily;		Teva

				Started On Hospital Day 6 As A Bridge To Compassionate Use Of Remdesivir; Two D		
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Teva
	Tocilizumab	S	Unknown	800 Milligram Daily; Given On Hospital Day 7 And 8		Not Reported
	Tocilizumab	S				Not Reported
	Remdesivir	S	Unknown	100 Milligram Daily; Off Label Use Of Remdesivir Started On Hospital Day 10; 100 Mg Daily For Five D		Not Reported
	Vincristine	C	Unknown			Not Reported
	Irinotecan	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18309024	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1829767		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Haemodynamic Instability; Hyperkalaemia; Nephropathy Toxic; Off Label Use; Pneumonia Bacterial; Sepsis; Stenotrophomonas Infection	Cotrimoxazole			S	Unknown			Teva
	Cotrimoxazole			S				Teva
	Mycophenolic Acid			S	Unknown	500 Milligram Daily;		Teva
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	10 Milligram Daily;		Not Reported
	Cefepime			S	Unknown			Not Reported
	Atracurium			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18309045	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200932049		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Vestibular Neuronitis	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18309204	EXPEDITED (15-DAY)		OT	PT-ABBVIE-20K-130-3575318-00		83 YR	Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Off Label Use	Lopinavir/Ritonavir			S	Oral	2cp 12/12h		Not Reported
	Azithromycin			S	Oral	Day 1 500mg Treatment Of Covid 19		Not Reported
	Hydroxychloroquine			S	Oral	Day 1: 400mg 12/12h		Not Reported
	Propofol			C	Intravenous (not otherwise specified)			Not Reported
	Remifentanil			C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
	Ketamine			C				Not Reported
	Esomeprazole			C				Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)			Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin Sodium			C				Not Reported

	Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	Not Reported
	Furosemide	C		Not Reported
	Human Serum Albumin	C	Intravenous (not otherwise specified)	Not Reported
	Quetiapine	C	Oral	Not Reported
	Methylprednisolone	C		Not Reported
	Lorazepam	C		Not Reported
	Aas	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18309339	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200625772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Malaise; Pain; Peripheral Swelling; Rheumatoid Arthritis; Somnolence; Visual Impairment	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18309500	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2020-US-1829868		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Herniation; Brain Oedema; Brain Stem Syndrome; Cerebral Haemorrhage; Coma; Off Label Use	Enoxaparin Sodium			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Apixaban			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18310512	EXPEDITED (15-DAY)		OT	NVSC2020FR260451			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Azithromycin			S	Unknown	500 Mg, Qd First Day		Novartis
	Azithromycin			S	Unknown	250 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Bid For First Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18310977	EXPEDITED (15-DAY)		OT	NVSC2020CA258628			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hand Deformity; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium	S	Unknown	Unk	Novartis
	Desoximetasone	S	Oral	Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg, Ot (1 Milligram)	Not Reported
	Methotrexate	S	Intra-arterial	25 Mg, Ot (25 Milligram)	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Ot (500 Milligram)	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Ot (25 Milligram)	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Ot (10 Milligram)	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Ot (40 Milligram)	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18310988	EXPEDITED (15-DAY)		OT	NVSC2020CA253877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone			S	Topical	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported
	Alendronic Acid			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Subcutaneous	500 Mg		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S				Not Reported
	Arava			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Apo Prednison	S	Oral	Unk		Not Reported
	Fosamax	S	Oral	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18311103	EXPEDITED (15-DAY)		OT	CA-ROCHE-2683845		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Drug Ineffective; Panniculitis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18311121	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200934728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Tylenol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported

	Levothyroxine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Oral	Not Reported
	Ramipril	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	11878759	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20151223430		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Confusional State; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Liver Function Test Increased; Muscular Weakness; Nausea; Off Label Use; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclic(Every 2 Weeks) 40 Mg/0.8 Ml		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Azathioprine Sodium	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Tocilizumab	S	Unknown	Not Reported
Cimzia	C	Unknown	Not Reported
Enbrel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	12222790	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-020922		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported

Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Fentanyl Citrate	S	Epidural		Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, 2 Every One Day	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S			Not Reported
	Apo Celecoxib	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Apo Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride;Perphenazine	S	Oral	10 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
	Omega 3 [Fish Oil;Tocopherol]	C	Unknown	1200 Milligram, Bid	Not Reported
	Multivitamin [Ascorbic Acid;Calcium Pantothenate;Ergocalciferol;Nicoti	C	Unknown	Unk	Not Reported
	Tecta	C	Unknown	40 Mg, Qd	Not Reported
	Diphenoxylate	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate	C	Unknown	1 Dosage Form, Qd	Not Reported

Vitamin D [Ergocalciferol]	C	Unknown	400 Unit, Qd	Not Reported
Actonel	C	Unknown	36 Milligram, Qwk	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram 1 Every 2 Hour	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Biotin;Calcium Carbonate;Colecalciferol;Folic Acid	C	Unknown		Not Reported
Acetaminophen W/Oxycodone	C	Unknown	1 Dosage Form Prn	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram 1 Every 1 Hour	Not Reported
Tylenol	C	Oral	1000 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Qd	Not Reported

Xeljanz	C	Unknown	5 Milligram	Not Reported
Vitamin B12 Aaa	C	Unknown		Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Vitamin A Nos	C	Unknown	Unk	Not Reported
Vitamin B 12 [Cyanocobalamin]	C	Unknown	Unk	Not Reported
Vitamin C Acid	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram 1 Every One Hour	Not Reported
Nexium [Esomeprazole Sodium]	C	Unknown	40 Milligram, Bid	Not Reported
Genteal [Hypromellose]	C	Unknown		Not Reported
Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	C	Unknown	1 Dosage Form, As Required	Not Reported
Perphenazine	C	Unknown	40 Milligram, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	1 Dosage Form, Prn	Not Reported
Vitamin E [Tocopherol]	C	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported

Epa Dha 720	C	Unknown	Unk	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown		Not Reported
Omega-3 [Salmo Salar Oil]	C	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Bid	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Cholecalciferol	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	1000 Milligram, Qd	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
D-Alpha Tocopheryl Acetate	C	Unknown	1200 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram, Bid	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	12689207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1434		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Surgery; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2 Every 1 Weeks	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2 Times/Week	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cyclosporine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not		Not Reported

			otherwise specified)	
	Infliximab	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Intramuscular	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	12912114	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20160308952		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Fatigue; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Amlodipine Besilate			C				Not Reported

	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Oral	Not Reported
	Lyrica	C	Oral	Not Reported
	Mavik	C	Unknown	Not Reported
	Olopatadine Hydrochloride	C	Ophthalmic	Not Reported
	Prednisone	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	12912721	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091699		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day	Not Reported
Folic Acid	S	Unknown	25 Gram	Not Reported
Folic Acid	S	Unknown	1 Gram	Not Reported
Folic Acid	S	Unknown	500 Gram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	12913352	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-037942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Breath Sounds Abnormal; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported

Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Unk	Not Reported
	Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported

Azathioprine	S	Unknown		Not Reported
Prednisone	C	Intracardiac	5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
Prednisone	C	Unknown	8.5 Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Alprazolam	C	Unknown	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Paroxetine	C	Unknown	Unk	Not Reported
Risedronate	C	Unknown	Unk	Not Reported
Simvastatin	C	Unknown	Unk	Not Reported
Telmisartan	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown		Not Reported
Iron Sucrose	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13063466	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0485		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Intolerance; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13070799	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2790		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypertension;	Methotrexate (Trade Name Unknown)			S	Oral	Dose Range From 20 Mg, 15 Mg, Than 10 Mg, Weekly		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	Dose Range From 20, 15, Than 10 Mg, Weekly		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name			S	Oral			Not Reported

Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Unknown)			
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not	Not Reported

		otherwise specified)		
Remicade	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Intravenous (not otherwise specified)	Monthly	Not Reported
Arava	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Golimumab	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Tocilizumab	S	Unknown		Not Reported
Desoximetasone	C	Unknown		Not Reported
Infliximab	C	Unknown		Not Reported
Infliximab	C	Unknown		Not Reported
Infliximab	C	Unknown		Not Reported

	Cortisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13114444	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20170105843		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Alopecia; Ankylosing Spondylitis; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Asthma; Basal Cell Carcinoma; Blood Iron Abnormal; Blood Parathyroid Hormone Decreased; Blood Test Abnormal; Body Temperature Decreased; Bone Lesion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Chest Pain; Chills; Condition Aggravated; Contraindicated Product Administered; Contusion; Cough; Deep Vein Thrombosis; Dermatitis; Diarrhoea; Diarrhoea; Disease Progression; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Enthesopathy; Erythema;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Motrin			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Benadryl			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Start Date: 5th Of Unspecified Month		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Start Date: 1st Of Unspecified Month		Not Reported

Fall; Fatigue; Feeling Abnormal; Gastric	Methotrexate Sodium	S	Subcutaneous	Start Date: 8th Of Unspecified Month	Not Reported
Disorder; Gastrointestinal Disorder; Gastrointestinal	Methotrexate Sodium	S	Subcutaneous		Not Reported
Pain; Granuloma Skin;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Headache; Heart Rate Increased; Hepatic	Methotrexate Sodium	S	Subcutaneous		Not Reported
Enzyme Abnormal;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Hypercalcaemia;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Hypersensitivity; Infection;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Inflammation; Influenza;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Infusion Related Reaction;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Joint Swelling; Lethargy;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Limb Discomfort; Loss Of Personal Independence In	Methotrexate Sodium	S	Subcutaneous		Not Reported
Daily Activities; Lower Respiratory Tract	Tocilizumab	S	Unknown		Not Reported
Infection; Morton'S Neuralgia; Muscular Weakness;	Tocilizumab	S	Unknown	Start Date: On 10th Of Unspecified Month In 2011.	Not Reported
Musculoskeletal Disorder;	Tocilizumab	S	Unknown		Not Reported
Musculoskeletal Stiffness;	Tocilizumab	S	Unknown		Not Reported
Mycotic Allergy; Nausea;	Tocilizumab	S	Unknown		Not Reported
Neoplasm Skin;	Actemra	S	Unknown		Not Reported
Neuropathy Peripheral; Off Label Use; Oral	Actemra	S	Unknown		Not Reported
Discomfort; Pain; Pain In Extremity; Panniculitis;	Actemra	S	Unknown		Not Reported
Peripheral Swelling;	Actemra	S	Unknown		Not Reported
Product Use Issue;	Actemra	S	Unknown		Not Reported
Productive Cough; Psoriatic Arthropathy;	Actemra	S	Unknown		Not Reported
Rash; Rash Pruritic; Red Blood Cell Sedimentation	Actemra	S	Unknown		Not Reported
Rate Increased; Respiratory Tract	Actemra	S	Unknown		Not Reported
Congestion; Rheumatoid Arthritis; Rheumatoid	Alendronate	S	Unknown		Not Reported
Nodule; Rhinorrhoea; Sciatica; Sinusitis; Skin	Alendronate	S	Unknown		Not Reported
Necrosis; Skin Ulcer; Speech Disorder;	Alendronate	S	Unknown		Not Reported

Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Treatment Failure; Ulcer	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral	4 Years	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Codeine	S	Unknown		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported

Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Rituximab	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Ergocalciferol	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Apo Ibuprofen	S	Oral		Not Reported
Apremilast	S	Unknown		Not Reported

Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Ciclosporin	S	Oral		Not Reported
Gold	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Infliximab	S			Not Reported
Infliximab	S			Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Azathioprine	S			Not Reported
Certolizumab Pegol	S	Vaginal		Not Reported
Hydroxychloroquine	S			Not Reported
Sulfasalazine	S			Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Prednisolone	C			Not Reported
Desoximetasone	C			Not Reported
Naproxen	C			Not Reported
Plaquenil /00072602/	C			Not Reported
Sulfasalazine	C			Not Reported
Symbicort	C			Not Reported
Tramadol Hydrochloride	C			Not Reported
Colchicine	C	Unknown		Not Reported
Dexlansoprazole	C	Unknown	Delayed Release	Not Reported
Febuxostat	C	Unknown		Not Reported

	Folic Acid	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported
	Mogadon	C	Unknown	Not Reported
	Oxycodone	C	Unknown	Not Reported
	Uloric	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13132615	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0240		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral	10 To 12.5 Milligram		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	10 To 17.5 Milligram		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	10 To 15 Millgram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Neoplasm Excision; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer			otherwise specified)		
	Tocilizumab	S	Unknown		Not Reported
	Rituxan	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13158922	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005391			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Anakinra			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13659278	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170611422		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Adverse Reaction; Arthralgia; Blood Iron Abnormal; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Contusion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; White Blood Cell Count Decreased	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intra-uterine	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Mycophenolate	S	Unknown	Not Reported
Mycophenolate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Pregabalin	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Piroxicam	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Ciclosporin	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Imuran /00001501/	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported

Rituximab	S	Intravenous drip	Not Reported
Azathioprine	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Unknown	Not Reported
Lyrica	S	Oral	Not Reported
Plaquenil /00072603/	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13846403	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070150		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Loss Of	Orencia			S	Unknown	200 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Enbrel	S	Subcutaneous	50 Mg, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Apo-Prednisone	S	Unknown	20 Ng, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 G, Q6mo	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Prednisone	S	Unknown	20 Ng, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 Gram, Q6mo	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	13875527	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2509			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Decreased; Viral Infection	Hydroxychloroquine		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Apo-Folic Acid		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Cymbalta		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	14502886	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007063		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Qmo		Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported

Methotrexate	S	Oral	25 Milligram, Qmo	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qd	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Remicade	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, 2 Every1day	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Apo-Hydroxyquine	S	Oral	400 Milligram, Qd	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2 Gram, Q6mo	Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Actonel	C	Unknown		Not Reported
Sulfasalazine	C	Oral	Unk	Not Reported
Sulfasalazine	C	Oral	500 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	14917261	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069816		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15242994	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1069		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Product Use Issue; Rash; Skin Mass; Therapy Non-Responder	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15408169	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180908328		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Simponi	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indomethacin	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Radioactive Gold	S	Unknown	Not Reported
	Indocid /00003801/	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

	Apo-Prednisone	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Cymbalta	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15569077	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3075		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	Extended Release	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Bupropion	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15648749	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181126693		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15749108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3822		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Cimzia	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Cyclical	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown	200mg:1 And A Half Pill	Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Cyclical, On Day 0 And Day 15	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Unknown		Not Reported
Gold	S	Other		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported

Apo-Hydroxyquine	S	Unknown		Not Reported
Actonel	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral	Cyclic	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Risedronate	S	Oral		Not Reported
Risedronate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15854681	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633525-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15930195	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2654210-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled		Not Reported

Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine	S	Syringe Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15957810	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190213510		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Nasopharyngitis; Serum Ferritin Decreased; Viral	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Upper Respiratory Tract Infection	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15964290	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014485		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Unknown	15 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	15 Milligram, Qwk	Not Reported
	Remicade	S	Unknown	40 Milligram	Not Reported
	Rituximab	S		Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	15978234	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Bupropion	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	16079967	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06102		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown Solution Intravenous		Not Reported
	Rituxan			S	Unknown	Unknown Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not	Unknown		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	16337732	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-048239		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Ibuprofen			S	Oral	600 Milligram		Bristol Myers Squibb
	Ibuprofen			S	Oral	600 Milligram, Qd		Bristol Myers Squibb
	Ibuprofen			S	Oral	Unk, 1 Every 1 Day		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, 4 Every 1 Week		Not Reported
	Apo Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Unknown	60 Milligram, 2 Every One Day		Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	15 Milligram,1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram, 4 Every1week		Not Reported

Methotrexate	S	Unknown	12 Milligram,4every1week	Not Reported
Methotrexate	S	Unknown	10 Milligram,4every 1week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,4every 1week	Not Reported
Methotrexate	S	Unknown	70 Milligram,1every1week	Not Reported
Otezla	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram,2every1day	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	25 Milligram,2every1week	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Days	Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown		Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram,2every1day	Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported

	Oxycodone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	16450974	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822464-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported
	Methylprednisolone Acetate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	16628388	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2863507-00		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported

Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17173636	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2019053782		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride			S				Ucb

Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Fibromyalgia; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Apo-Prednisone	S			Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram Solution	Ucb
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Oral	25 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Phthalylsulfathiazole	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
Prednisone	S	Oral		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Enbrel	S	Subcutaneous	50 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	4 Milligram	Not Reported
Leflunomide	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S			Not Reported
Stelara	S	Subcutaneous		Not Reported
Xeljanz	S			Not Reported
Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
Alendronate Sodium;Alendronic Acid	S		Intracorpus	Not Reported
Cortisone Acetate	S		25 Milligram	Not Reported
Cortisone Acetate	S	Oral		Not Reported
Prednisone	S	Oral	25 Milligram	Not Reported
Golimumab	S			Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Cortisone Acetate	S	Endocervical		Not Reported
Diclofenac	S			Not Reported
Simponi	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Alendronate Sodium	S			Not Reported
Cortisone Acetate	S			Not Reported
Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported

	Sulfasalazine	S	Oral	1000 Milligram	Not Reported
	Sulfathalidine	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Paracetamol	C			Not Reported
	Caffeine Citrate	C			Not Reported
	Lisinopril	C			Not Reported
	Colecalciferol	C			Not Reported
	Ibuprofen	C			Not Reported
	Salazopyrin	C			Not Reported
	Codeine Phosphate	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17223484	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3215049-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17391221	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170826218		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Abdominal Distension; Adverse Reaction; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nail Disorder; Nausea; Off Label Use; Onychomycosis; Pain; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sleep Disorder; Treatment Failure	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Cosentyx			S	Unknown			Not Reported

	Certolizumab Pegol	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Tocilizumab	S		Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Apo Prednison	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rheumatrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17558247	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316516		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tocilizumab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Celebrex	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Vioxx	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Erelzi	S	Subcutaneous	Not Reported
Desoximetasone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C		Not Reported
Methotrexate	C	Oral	Not Reported
Methotrexate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17562437	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
	Loperamide	C	Oral	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk, Tid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17566419	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318563		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Bimatoprost	C	Ophthalmic	Not Reported
	Nexium /01479302/	C	Unknown	Not Reported
	Suphedrine /00005601/	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Esomeprazole Sodium	C	Unknown	Not Reported
	Lumigan Rc	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17572198	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024000			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported

Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris	S			Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S			Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	5 Milligram, 1 Every 2 Weeks	Not Reported
	Xeljanz	C	Oral	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17579770	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327863		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Constipation; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Fatigue; Fibromyalgia; Hypersensitivity; Insomnia; Iodine Allergy; Joint Swelling; Nausea; Oedema; Off Label Use; Pain; Pain In Extremity; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Synovitis; Vomiting	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	M-Eslon			C	Unknown			Not Reported

Morphine	C			Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Statex	C	Unknown		Not Reported
Hydrodiuril	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17579773	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200327868		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anaphylactic Shock; Arthralgia; Arthritis; Bedridden; Bone Erosion; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Exostosis; Fibromyalgia; Foot Deformity; Foot Fracture; Fracture; General Physical Health Deterioration; Hepatitis; Immobile; Joint Dislocation; Joint Stiffness; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoarthritis; Osteoporosis; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Skin Disorder; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	3.0 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Prednisolone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prolia	S	Subcutaneous		Not Reported
Prolia	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Minims Prednisolone Sodium Phosphate	S	Ophthalmic	0.5%	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Risedronate Sodium	S	Unknown		Not Reported
Risedronate Sodium	S	Oral		Not Reported
Risedronate Sodium	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Otezla	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Sirukumab	S	Unknown		Not Reported

Xeljanz	S	Oral	Not Reported
Azathioprine	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Cyclobenzaprine	C		Not Reported
Desoximetasone	C		Not Reported
Prednisone Acetate	C		Not Reported
Tylenol /00020001/	C		Not Reported
Allopurinol	C	Unknown	Not Reported
Hydroxychloroquine	C		Not Reported
Methotrexate	C		Not Reported
Prolia	C	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported
Calcium	C		Not Reported
Magnesium	C		Not Reported
Amlodipine	C	Unknown	Not Reported
Hydrochlorothiazide W/Olmesartan Medoxomil	C		Not Reported
Naproxen	C		Not Reported
Varicella Zoster Vaccine Live (Mav/06)	C		Not Reported
Vitamin D /00107901/	C		Not Reported
Erelzi	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17579775	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327856		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Arthralgia; Arthropathy; Back Disorder; Blood	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Pressure Increased; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Feeling Abnormal; Gait Disturbance; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17606950	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318841		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Simponi			S	Subcutaneous	Therapy Duration: 486		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab, Recombinant			S	Unknown			Not Reported
	Infliximab, Recombinant			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Subcutaneous	Not Reported
Azathioprine	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Minocycline	C	Unknown	Not Reported
Penicillamine	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported

Prednisolone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Tocilizumab	C	Unknown		Not Reported
Actemra	C	Unknown		Not Reported
Phenylbutazone	C	Unknown		Not Reported
Tofacitinib	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17651850	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316464		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Simponi			S	Subcutaneous			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Tylenol /00020001/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17706132	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600414		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17893830	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-028687		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Neutropenia; Thrombocytopenia	Amiodarone			S	Unknown	Unk		Aurobindo
	Atorvastatin			S	Unknown	Unk		Not Reported

	Azithromycin Film-Coated Tablets	S	Unknown	500 Milligram	Aurobindo
	Azithromycin Film-Coated Tablets	S	Oral	250 Milligram, Once A Day	Aurobindo
	Bisoprolol	S	Unknown	Unk	Aurobindo
	Furosemide	S	Unknown	Unk	Aurobindo
	Paroxetine	S	Unknown	Unk	Aurobindo
	Enoxaparin Sodium	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	600 Milligram	Not Reported
	Plaquenil	S	Oral	200 Milligram, Once A Day	Not Reported
	Sarilumab	S	Subcutaneous	400 Milligram, Total	Not Reported
	Alprazolam	C	Unknown	Unk	Not Reported
	Amlor	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Eplerenone	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Hydroxyzine	C	Unknown	Unk	Not Reported
	Kcl	C	Unknown	Unk	Not Reported
	Lansoprazole	C	Unknown	Unk	Not Reported
	Levothyroxine	C	Unknown	Unk	Not Reported
	Racecadotril	C	Unknown	Unk	Not Reported
	Seresta	C	Unknown	Unk	Not Reported
	Tamsulosin	C	Unknown	Unk	Not Reported
	Melatonine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17896405	EXPEDITED (15-DAY)		OT	FR-SA-2020SA151461			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage; Metastases To Eye; Off	Depakote			S	Unknown	2 Df, Bid, 1 Tablet In The Morning And 1 Tablet In		Not Reported

Label Use; Product Availability Issue				The Evening	
	Plaquenil	S	Unknown		Sanofi
	Plavix	S	Unknown		Sanofi
	Xanax	C			Not Reported
	Corenitec	C			Not Reported
	Imovane	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17909409	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046330		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported

Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Fosamax	S	Oral		Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown		Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydrocortisone	S	Oral		Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Cutaneous	Unk	Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Oral	1 Dosage Form, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram (2 Every 1 Day)	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram (2 Every 1 Day)	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17917269	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17922289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-049300		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, 1 Every 1		Not Reported

				Day	
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 1 Every 1 Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Ketorolac	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17956267	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-187262			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Naproxen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Weeks, 1 Every 2 Weeks		Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported

Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Prednisone	S	Oral	1 Every 1 Days	Not Reported
	Sulfasalazine	S	Oral	1 Every 1 Days	Not Reported
	Triamcinolone	S	Unknown	Suspension Intra- Articular	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo Prednisone	S	Oral	2 Every 1 Days, Tab 5mg	Not Reported
	Apo-Naproxen	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Apo Prednisone	S	Oral	2 Every 1 Days, Tab 5mg	Not Reported
	Enbrel	S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	17983793	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1796355		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Ivax
	Methotrexate			S	Subcutaneous			Barr
	Celecoxib			S	Oral			Teva
	Celecoxib			S				Teva
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure			otherwise specified)		
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	500 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram Daily;	Not Reported
	Apo-Gabapentin	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Nortriptyline	S	Unknown		Not Reported
	Nortriptyline	S	Unknown		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Aclasta	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Fentanyl	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram Daily;	Not Reported
	Fish Oil	C	Unknown		Not Reported
	Nasonex	C	Unknown		Not Reported
	Omega 3-6-9 [Fish Oil]	C	Unknown		Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Vitamin B3	C	Unknown		Not Reported
	Genteal [Carmellose Sodium;Hypromellose]	C			Not Reported
	Lomotil	C	Unknown	2.5 Milligram Daily;	Not Reported

	Nortriptyline Hydrochloride	C	Oral	240 Gbq Daily;	Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Risedronate Sodium	C			Not Reported
	Trazodone	C	Oral	1200 Milligram Daily;	Not Reported
	Tylenol	C	Oral	24000 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	80 Milligram Daily;	Not Reported
	Omega-3 Fatty Acids	C	Unknown	2400 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18019768	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-056187		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18042830	EXPEDITED (15-DAY)		OT	CA-ACCORD-191100		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia;	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported

Nausea; Thrombosis; Treatment Failure	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Sulfasalazine		S			Not Reported
	Methotrexate		S	Subcutaneous		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18090770	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3759		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Naproxen	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18137124	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELLTRION INC.-2020CA024983			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid	Rituximab (Unknown)			S	Unknown	1000 Milligram, Bid		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Days		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram 4 Every One Week		Not Reported
	Apo Ibuprofen			S	Oral	600 Mg, Unk		Not Reported
	Apo Ibuprofen			S	Oral	Unk		Not Reported
	Apremilast			S	Oral	30 Mg, 2x/Day		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported

Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue	Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
	Apremilast	S	Unknown	60 Milligram, 2 Every 1 Days	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S		25 Milligram	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, 2 Every 1 Weeks	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	40 Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported

Disorder; Treatment Failure; Ulcer; Urticaria	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown	15.0 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram 4 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram 4 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram 4 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	70.0 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram 4 Every 1 Years	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Mg, Q4h	Not Reported
	Motrin [Ibuprofen]	S	Oral	600.0 Mg, Unk	Not Reported
	Motrin [Ibuprofen]	S		6 Df, 1x/Day	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Motrin [Ibuprofen]	S	Oral	Unk, Qd	Not Reported
	Motrin [Ibuprofen]	S	Oral	600.0 Milligram, 1 Every 1 Days	Not Reported
	Motrin [Ibuprofen]	S	Oral	1 Every 1 Days	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S			Not Reported
	Otezla	S	Oral	30 Mg, Bid	Not Reported
	Otezla	S	Oral	60 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Remicade	S	Intravenous drip	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Tocilizumab	S	Unknown	680.0 Milligram	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Etanercept	S		Unk	Not Reported
Etanercept	S		Unk	Not Reported
Infliximab Hospira	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
Infliximab Hospira	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Infliximab Hospira	S	Oral	Unk	Not Reported
Ibuprofen	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Ibuprofen	S	Oral	600 Mg, Q4h	Not Reported
Ibuprofen	S	Oral	600 Milligram	Not Reported
Ibuprofen	S	Oral	600 Milligram	Not Reported
Ibuprofen	S	Oral	Unk Unk, Qd	Not Reported

Methotrexate Sodium	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Not Reported
Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate Sodium	S	Unknown	12.5mg, 4 Times/Wk, .1096mg, 4 In 1 Years, .1315mg, 4 In 1 Years, 10 Mg, 12mg, 17.5mg, 4 Times/Wk, 1	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Apo-Cyclosporine	S	Unknown	Unk	Not Reported

Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Celebrex	S	Oral	200 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral		Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported

Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Oral	50 Milligram	Not Reported
Nitrazepam	C	Oral	5.0 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Uloric	C	Oral	160 Mg, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Acide Folique	C		Unk	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Naproxen	C		500 Milligram	Not Reported
Cannabis Sativa	C		Unk	Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported

	Risedronate Sodium			C	Oral	35 Milligram, Qwk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18201741	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Pantoprazole			S	Oral	1 Dosage Form, Qd		Apotex
	Pantoprazole			S	Unknown	Unk		Apotex
	Meloxicam			S	Oral	7.5 Milligram, Qd		Apotex
	Diclofenac			S	Oral			Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Methotrexate			S	Oral	10 Milligram, Q.Wk.		Apotex
	Methotrexate			S	Subcutaneous	25 Milligram, Q.Wk.		Apotex
	Methotrexate			S	Oral	4 Dosage Form, Q.Wk.		Apotex
	Cosentyx			S	Oral	300 Milligram, Q.M.T.		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Leucovorin Calcium			S	Oral	5 Milligram, Q.Wk.		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Salbutamol			C		Unk		Not Reported
	Mometasone Furoate			C	Unknown	Unk		Not Reported
	Mar-Pantoprazole			C	Unknown	Unk		Not Reported
	Fluticasone Propionate			C		Unk		Not Reported
	Diltiazem Hydrochloride			C	Oral	240 Milligram		Not Reported
	Tramadol Hydrochloride			C	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18205157	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025582			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Vomiting; X-Ray Abnormal	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1 Every 1 Day		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, 1 Every 1 Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	5 Mg, 1 Every 1 Day		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S	Unknown	10 Mg		Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18226860	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016868			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Doxycycline		S	Unknown	50 Milligram	Apotex
	Hydroxychloroquine		S	Unknown		Apotex
	Leflunomide		S	Unknown	20 Milligram, Qd	Apotex
	Enbrel		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Prednisone		C	Unknown	10 Milligram, Qd	Not Reported
	Simponi		C	Subcutaneous	Unk	Not Reported
	Xeljanz		C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18243758	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318939		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18245859	EXPEDITED (15-DAY)			CA-ORION CORPORATION ORION PHARMA-20_00010694		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18251488	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020181649		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister;	Cetirizine Hydrochloride			S	Unknown	10 Mg		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	10 Mg		Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Mg		Glaxosmithkline

Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Cutaneous	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Diclofenac	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Mg	Glaxosmithkline
	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Mg	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate	S	Oral	200 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	5 Mg	Not Reported
	Xeljanz	S	Unknown	5 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg	Not Reported
	Phthalylsulfathiazole	S	Oral	1000 Mg	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Mg	Not Reported

	Actemra	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab	S	Unknown	Unk		Not Reported
	Golimumab	S	Subcutaneous	Unk		Not Reported
	Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18253973	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020181466		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Asthenia; Blood Cholesterol Increased; Bursitis; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Dry Mouth; Exposure During Pregnancy; Facet Joint Syndrome; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Inflammation; Infusion Related Reaction; Intentional Product Use	Cetirizine Hydrochloride			S	Unknown	10 Mg		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	50 Mg		Glaxosmithkline
	Paracetamol			S	Unknown	650 Mg		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	5 Mg		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported

Issue; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Pemphigus; Pericarditis; Peripheral Swelling; Peripheral Venous Disease; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Type 2 Diabetes Mellitus	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Tylenol (Paracetamol)	S	Unknown	650 Milligram, 2x/Day (Bid)	Not Reported
	Salazopyrine	S	Oral	2 Gram, 2x/Day (Bid)	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Winpred	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg	Not Reported
	Sulfasalazine	S	Oral	1000 Mg	Not Reported
	Sulfasalazine	S	Oral	2 G	Not Reported
	Sulfasalazine	S	Oral	2 G	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported

Sulfathalidine	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Subcutaneous	Unk		Not Reported
Topicort Lp 0.5%	S	Subcutaneous	Unk		Not Reported
Rituxan	S	Subcutaneous	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Glaxosmithkline
Pantoprazole	C				Glaxosmithkline
Domperidone	C	Unknown	Unk		Glaxosmithkline
Risedronate Sodium	C	Unknown	Unk		Not Reported
Calcium Carbonate + Vitamin D	C	Unknown	Unk		Not Reported
Gabapentin	C	Unknown	Unk		Not Reported
Pantoprazole Sodium	C	Unknown	Unk		Not Reported
Nifedipine	C	Unknown	Unk		Not Reported
Lipitor	C	Unknown	Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Citalopram	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18264444	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020182510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk Milligram		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline

Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Hydrocortisone Acetate	S	Unknown	Unk	Glaxosmithkline
	Cortisone Acetate	S	Unknown	25 Milligram	Glaxosmithkline
	Cortisone Acetate	S	Unknown	5 Milligram	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Subcutaneous	Unk	Glaxosmithkline
	Desoximetasone	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Oral	25 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	10 Mo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Alendronate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported

	Prednisone	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18271478	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200919284		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18273180	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA249040		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg		Not Reported
	Sulfasalazine			S	Oral	500 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Tofacitinib	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Cortison	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Flumetasone Pivalate	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Oral	1000 Mg	Not Reported
Phthalylsulfathiazole	S	Oral	500 Mg	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg	Not Reported
Apo-Prednisone	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Topicorten	S	Cutaneous	Unk	Not Reported
Plaquenil	S	Oral	400 Mg, Qd	Not Reported
Apo-Folic Acid	S	Unknown	5 Mg	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18279487	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200922512		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Neuropathy Peripheral; Retinopathy	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18288038	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010847		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; C-Reactive Protein Increased; Diarrhoea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Amiodarone			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Colchicine			C	Unknown			Not Reported
	Entresto			C	Unknown			Not Reported
	Ezetimibe			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18300414	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027629			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1.0 Gram, 2 Every 1 Day	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18301829	EXPEDITED (15-DAY)		OT	NVSC2020CA253985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	25 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Methotrexate			S	Oral	1 Dosage Form		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G		Not Reported
	Alendronate Sodium			S	Oral	5 Mg		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Enbrel			S	Subcutaneous	40 Mg		Not Reported
	Enbrel			S	Subcutaneous	40 Mg		Not Reported

Enbrel	S	Subcutaneous	40 Mg		Not Reported
Golimumab	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	5 Mg		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309189	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020368477			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Eye Disorder; Hypertension; Pneumonia; Post Procedural Infection; Restless Legs Syndrome	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Rofact (Rifampicin)			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Chlormezanone			C	Unknown	Unk		Not Reported
	Colchicine			C	Unknown	Unk		Not Reported
	Dexilant			C	Unknown	Unk		Not Reported
	Diclofenac Sodium			C	Unknown	Unk		Not Reported
	Hydromorph Contin			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

	Quetiapine		C	Unknown	Unk	Not Reported
	Trazodone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309264	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001487			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Dyspnoea; Ejection Fraction Decreased; Left Ventricular Hypertrophy; Oedema Peripheral; Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309311	NON-EXPEDITED			US-ADVANZ PHARMA-202009008741			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine			S				Concordia
	Xeljanz Xr 11 Mg Tablet			C	Oral	11 Mg, Qd With Food		Not Reported
	Prednisone 10 Mg Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309323	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2020-049350		83 YR	Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Covid-19 Treatment; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	250 Milligram, Once A Day (D1 500mg)		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day (D1: 400mg 12/12h)		Not Reported
	Lopinavir;Ritonavir			S	Oral	4 Dosage Form, Once A Day (2cp 12/12h)		Not Reported

Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Remifentanil	C	Intravenous (not otherwise specified)	Unk	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	Unk	Not Reported
Ketamine	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Ipratropium Bromide	C	Respiratory (inhalation)	Unk	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Enoxaparin Sodium	C	Unknown	Unk	Not Reported
Piperacillin;Tazobactam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Human Serum Albumin	C	Intravenous (not otherwise specified)	Unk	Not Reported
Quetiapine	C	Oral	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	Unk	Not Reported
Aas	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309393	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202009008752			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aphthous Ulcer; Back Pain; Constipation; Depression; Dysgeusia; Facial Pain; Fibromyalgia; Inflammation; Liver	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Ferrous Fumarate			S	Unknown	300 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qod		Not Reported

Function Test Increased; Malaise; Migraine; Neuropathy Peripheral; Osteoarthritis; Paraesthesia; Photosensitivity Reaction; Polyarthritis; Road Traffic Accident; Systemic Lupus Erythematosus; Therapeutic Response Decreased	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Methotrexate	S	Unknown	20 Mg, Weekly	Not Reported
	Methotrexate	S			Not Reported
	Imuran	S	Unknown	Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Hydrochlorothiazide	C		Unk	Not Reported
	D	C		Unk	Not Reported
	Maxalt	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tiazac	C		Unk	Not Reported
	Salazopyrin	C		Unk	Not Reported
	Tramacet	C		Unk	Not Reported
	Vit D	C		Unk	Not Reported
	Omega 3	C		Unk	Not Reported
	Amitriptyline	C		Unk	Not Reported
	Tramadol	C		Unk	Not Reported
	Cellcept	C		Unk	Not Reported
	Arthrotec	C		Unk	Not Reported
	Oxycocet	C		Unk	Not Reported
	Fiorinal	C		Unk	Not Reported
	Temazepam	C		Unk	Not Reported
	Topamax	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309396	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202009008750			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Brenzys			S	Unknown	Unk		Not Reported

	Methotrexate Sodium	C	Unk		Not Reported
	Synthroid	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309410	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202009008823			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Arthrotec			C		Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309603	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06428		47 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenic Syndrome; Ocular Myasthenia; Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Single Dose		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309737	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06340		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309747	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06341		53 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309748	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06339		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Ampicillin			C	Intracardiac	Unk		Not Reported
	Gentamicin			C	Intracardiac	Unk		Not Reported
	Kaletra			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18309960	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-221935		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy	Hydroxychloroquine			S	Unknown	200 Milligram, Daily		Ipca
	Methotrexate			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310196	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP018124		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Allopurinol	S	Unknown	Unk	Apotex
	Apo-Amitriptyline	S	Unknown	Unk	Apotex
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Diclofenac	S	Topical	Unk	Apotex
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Apo-Naproxen	S	Unknown	Unk	Apotex
	Apo-Prednisone	S	Unknown	5 Milligram	Apotex
	Celecoxib	S	Unknown	Unk	Apotex
	Celecoxib	S			Apotex
	Diclofenac Potassium	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Misoprostol	S	Unknown	Unk	Not Reported
	Nifedipine	S	Unknown	Unk	Apotex
	Pregabalin	S	Unknown	Unk	Not Reported
	Winpred	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride;Perphenazine	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Celebrex	S			Not Reported
	Diclofenac Sodium;Misoprostol	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Q.Wk.	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported

	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	750 Milligram, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310220	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830930		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Azathioprine			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Medroxyprogesterone Acetate			S	Unknown			Barr
	Oxycodone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Elavil			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Depo Provera	C	Intramuscular	Not Reported
	Kineret	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310263	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830999		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methyl Salicylate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310315	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831082		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr

Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310335	EXPEDITED (15-DAY)		OT	CH-LUPIN PHARMACEUTICALS INC.-2020-06470		62 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Fibrinogen Increased; Hepatocellular Injury; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Atazanavir			S	Unknown	Unk		Not Reported
	Unfractionated Heparin			C	Unknown	Unk (Standard-Dose)		Not Reported
	Piperacillin/Tazobactam			C	Intracardiac	Unk		Not Reported
	Remdesivir			C	Intracardiac	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310336	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027840			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	1.0 Gram	Not Reported
	Celebrex	S	Unknown	200.0 Milligram	Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram, 1 Every 1 Day	Not Reported
	Methotrexate	S	Subcutaneous	1 Every 1 Week	Not Reported
	Naproxen	S	Unknown	500.0 Milligram, 2 Every 1 Day	Not Reported
	Orencia	S	Subcutaneous	150.0 Milligram, 1 Every 1 Month	Not Reported
	Simponi	S	Subcutaneous	50.0 Milligram, 1 Every 1 Month	Not Reported
	Sulfasalazine	S	Unknown	500.0 Milligram, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310446	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment	Cetirizine			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Failure; Wound	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Gram	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Q.12h	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310552	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP018039		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Amlodipine			S	Oral	5 Milligram, Qd		Apotex
	Amlodipine			S	Unknown	Unk		Apotex
	Amlodipine			S	Oral	Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Gliclazide			S	Unknown	Unk		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Asacol			S	Unknown	800 Milligram, Tid		Not Reported

Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Humira	S	Subcutaneous	Unk	Not Reported
	Mesalazine	S	Oral	800 Milligram, Tid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Oral	30 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tylenol	C	Unknown	500 Milligram	Not Reported
	Vitamin D3	C	Unknown	Unk, Qd	Not Reported
	Depo-Medrol	C	Intra-articular	120 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310553	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava	S	Oral	20 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	25 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk Unk, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

Stelara	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, Q12h		Not Reported
Sulfathalidine	S	Unknown			Not Reported
Topicort [Desoximetasone]	S	Subcutaneous			Not Reported
Xeljanz	S	Unknown	5 Milligram, Q12h		Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown			Not Reported
Salazopyrina	C	Unknown			Not Reported
Tofacitinib Citrate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310823	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-06468		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Cerebral Haemorrhage; Cerebral Venous Thrombosis; Hypotension; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18310829	NON-EXPEDITED			US-TEVA-2020-US-1831350			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Vulvovaginal Mycotic Infection; Vulvovaginal Swelling	Hydroxychloroquine Sulfate			S	Unknown	She Took A Daily Dose Anywhere Between 50-150 Mg		Teva
	Clarithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311120	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00009360		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Prednisone	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311342	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3576208-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cystitis; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Hyperphagia; Hypothyroidism; Inappropriate Schedule Of Product Administration; Infection; Inflammation; Intentional Dose Omission; Nasopharyngitis; Off Label Use; Pathogen Resistance; Peripheral Swelling; Pulmonary Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Root Canal Infection; Salt Craving; Tooth Abscess	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Drug Started Prior To 2013		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311459	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-06358		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311467	EXPEDITED (15-DAY)		HO, LT, OT	FR-LUPIN PHARMACEUTICALS INC.-2020-06357		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Torsade De Pointes	Hydroxychloroquine			S	Oral	200 Milligram, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311500	EXPEDITED (15-DAY)		DE	MA-PFIZER INC-2020362775		70 YR	Male	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytokine Storm; Drug Ineffective For Unapproved Indication; Multiple Organ Dysfunction Syndrome; Off Label Use	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Oxygen			S		12 L (12 L/Min)		Not Reported
	Oxygen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311651	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311684	EXPEDITED (15-DAY)		OT	CA-ACCORD-202538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pain; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Oral	1 Every 1 Days		Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Orencia	S				Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Folic Acid	C	Oral			Not Reported
Leflunomide	C				Not Reported
Prednisone	C	Oral			Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311772	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018240756		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Intentional Product Use	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Glaxosmithkline
	Diclofenac			S	Unknown	50 Milligram		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hcl			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	25 Milligram, Weekly (Qw)		Glaxosmithkline
	Desoximetasone			S	Subcutaneous	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	0.5 Milligram		Glaxosmithkline
	Folic Acid			S	Subcutaneous	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	3 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Hydrocortisone Acetate			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Not Reported

Issue; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Cimzia	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Since 4 Years	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous drip	Unknown Dose	Not Reported
	Methotrexate	S	Oral	15 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Salazopyrine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported

Sarilumab	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Winpred	S	Oral	Unk	Not Reported
Tofacitinib	S	Oral	5 Milligram, Weekly (Qw)	Not Reported
Tofacitinib	S	Unknown	5 Milligram, Once Daily (Qd)	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S	Unknown	5 Milligram	Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
Enbrel	S	Subcutaneous	20 Milligram	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported
Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported

Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Dextropropoxyphene + Acetaminophen	S	Unknown	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Stelara	S	Subcutaneous	45 Unk	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Topicort (Desoximetasone)	S	Subcutaneous	Unk	Not Reported
Topicort (Desoximetasone)	S	Oral	Unk	Not Reported
Adalimumab	S	Unknown	40 Milligram	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	Unk	Not Reported
Abatacept	S	Subcutaneous	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Stelara	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Apremilast	S	Unknown	3 Milligram, 2x/Day (Bid)	Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Prednisone	S	Oral	40 Milligram	Not Reported
Prednisone	S			Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Diclofenac	C	Unknown	Unk	Glaxosmithkline
	Caffeine + Codeine + Paracetamol	C	Unknown	Unk	Glaxosmithkline
	Xeljanz	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311927	EXPEDITED (15-DAY)		OT	CA-ACCORD-202602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Oral			Accord
	Alendronate Sodium/Alendronic Acid			S	Oral			Accord
	Hydroxychloroquine			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil			S		1 Every 1 Days		Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1 Every 12 Hours	Not Reported
	Tocilizumab	S			Not Reported
	Tofacitinib	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311956	EXPEDITED (15-DAY)		OT	CA-ACCORD-202542		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown			Accord
	Actemra			S				Not Reported
	Apo-Leflunomide			S		1 Every 1 Days		Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Abatacept			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Methotrexate			S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311959	EXPEDITED (15-DAY)		HO	CA-ACCORD-202603		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Every 1 Weeks		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S				Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312022	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3578091-00		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported

Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Methotrexate	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Infliximab	S	Unknown	Not Reported
	Infliximab	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312109	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202009008805			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibrin D Dimer Increased; Melaena; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Bid		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	1 Mg/Kg (80 Mg) Subcutaneous (Sq) Injection		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg (0.5 Mg/Kg) Sq Q12h		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Azithromycin For Injection Usp 500mg			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Azithromycin 250mg Oral			S	Oral	250 Mg, Qd		Not Reported
	Methylprednisolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312324	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Oral	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Alendronate			S	Oral	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312339	EXPEDITED (15-DAY)		OT	CA-ACCORD-202568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312369	EXPEDITED (15-DAY)		HO, OT	TR-APPCO PHARMA LLC-2091151		47 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Myasthenia; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312392	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831185		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312393	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831157		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312417	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Methotrexate			S	Unknown			Barr

Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Barr
	Diclofenac Sodium	S	Unknown	Actavis
	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312540	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug	Diclofenac			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine [Cetirizine]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Topicorten	S	Subcutaneous		Not Reported

	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Zyrtec	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Ml Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

	Adalimumab	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312695	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831176		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312697	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831143		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Alendronate Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Cortisone Acetate	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312698	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-076780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd (7 Years)		Not Reported

Failure	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid, Two Years	Not Reported
	Methotrexate	S	Oral	20 Milligram,One Every Two Weeks ,11 Every One Week	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312755	EXPEDITED (15-DAY)		HO	DK-UCBSA-2020036460		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Meningoencephalitis; Keratitis	Cimzia			S		Unk		Ucb
	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Ucb
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, Once Daily (Qd)		Not Reported
	Methotrexat Ebewe [Methotrexate]			S	Oral	Strength: 2,5 Mg		Not Reported
	Salazopyrin			C		Unk		Not Reported
	Salazopyrin			C		Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312762	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830655			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Kevzara			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312908	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1830940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Azathioprine Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Subcutaneous	Not Reported
	Tocilizumab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313033	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1830652		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313123	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020367478		3 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunodeficiency; Off Label Use; Product Use In	Zithromax			S	Oral	Unk		Pfizer

Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313160	EXPEDITED (15-DAY)		OT	NVSC2020CA261067		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Movement Disorder; Pain; Tuberculosis	Voltaren			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-076828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313243	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1081506		47 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticarial Vasculitis	Ceftriaxone			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Unknown			Mylan
	Enoxaparin			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313380	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-521		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Cardiomyopathy; Heart Valve Incompetence; Toxicity To Various Agents	Hydroxychloroquine		S	Unknown		Hikma
	Lansoprazole		C	Unknown	Unknown	Not Reported
	Abatacept		C	Unknown	Unknown	Not Reported
	Adalimumab		C	Unknown	Unknown	Not Reported
	Methotrexate		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313492	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Intra-arterial			Barr
	Alendronate Sodium			S	Oral			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Oral			Actavis
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochlorid/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochlorid/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831814		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown			Not Reported
Rituximab	S	Intravenous drip			Not Reported
Advil [Ibuprofen]	C				Not Reported
Folic Acid	C	Unknown			Not Reported
Ketorolac	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported
Naproxen	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313522	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831227		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313650	EXPEDITED (15-DAY)		DE, OT	NVSC2020ES260513			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Sudden Death	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313651	EXPEDITED (15-DAY)		LT	NVSC2020ES261451		91 DAY	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Seizure	Hydroxychloroquine			S	Unknown	6.5 Mg/Kg, Per Day		Novartis
	Levetiracetam			S	Unknown	28 Mg/Kg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313876	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP018325			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Atorvastatin			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	25 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q.M.T.		Not Reported
	Alprazolam			C	Unknown	1 Milligram		Not Reported

Folic Acid	C	Unknown	5 Milligram		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	5 Milligram, Qd		Not Reported
Naprosyn [Naproxen Sodium]	C	Unknown	500 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18313914	EXPEDITED (15-DAY)		OT	NVSC2020DE257523		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia	Methotrexate			S	Unknown	20 Mg, 3 Years Ago		Novartis
	Quensyl			S	Unknown	3 Years Ago		Not Reported
	Folsan			C	Unknown	3 Years Ago		Not Reported
	Prednisolone			C	Unknown	2.5 Mg 3 Years Ago		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18314057	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070700		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Off Label Use; Treatment Failure	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Subcutaneous	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18314123	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-06467		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Venous Thrombosis; Hydrocephalus; Intraventricular Haemorrhage; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18314314	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-079134			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Methotrexate	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Tocilizumab	S	Unknown	160 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18314358	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-079126			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S				Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Methotrexate	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S				Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S				Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Ilaris	S				Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S				Not Reported
Arava	S	Oral	Unk		Not Reported
Cannabis Sativa	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Minocycline	S	Unknown	Unk		Not Reported
Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Milligram, 1 Every 2 Weeks		Not Reported
Xeljanz	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18314443	NON-EXPEDITED			US-PFIZER INC-2020368637		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Delayed	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18314933	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA259875		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Anxiety; Arthropathy; C-Reactive Protein; Chest Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Musculoskeletal Pain; Pain; Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Urticaria; Urticaria; Wound	Diclofenac			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Acetaminophen			S	Unknown	10 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Paracetamol			S	Unknown	10 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Alendronic Acid			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg		Not Reported
	Phthalylsulfathiazole			S	Oral	500 Mg		Not Reported

Prednisone	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Oral	500 Mg		Not Reported
Tocilizumab	S	Unknown			Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid		Not Reported
Sulfathalidine	S	Oral	500 Mg		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Lansoprazole	C	Unknown	Unk		Not Reported
Ascorbic Acid	C	Unknown	Unk		Not Reported
Glucosamine	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Youplus Vitamin C	C	Unknown	Unk		Not Reported
Lansoprazole	C	Unknown	Unk		Not Reported
Lorazepam	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported
Salmon Oil	C	Unknown			Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18315031	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026694			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, 2 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tramadol	C	Unknown	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18315040	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027001			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18315041	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027015			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100.0 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Mg		Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18315096	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026940			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	11618911	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477033-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Angioedema; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Salicylates			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	13145130	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1000		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported

Arava	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Ciclosporine	S	Unknown		Not Reported
Ciclosporine	S	Unknown		Not Reported
Ciclosporine	S	Unknown		Not Reported
Ciclosporine	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Cyclical	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Imuran	S	Unknown		Not Reported
Imuran	S	Unknown		Not Reported
Imuran	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported

Plaquenil	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Cyclosporine	S	Oral		Not Reported
Apo-Cyclosporine	S	Oral		Not Reported
Apo-Cyclosporine	S	Oral		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown	Cyclic	Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Tocilizumab	S	Unknown		Not Reported

	Sodium Aurothiomalate	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cyclosporin	S	Oral	Not Reported
	Cyclosporin	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	15388757	EXPEDITED (15-DAY)		DS, LT, OT	CA-ROCHE-2182492		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	365.0 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wheezing; Wound	Enbrel	S	Subcutaneous	Solution For Injection	Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	4015.0 Days	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	365 Days	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral	365 Days	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral	1 Df	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported

Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous	335.0 Days	Not Reported
Orencia	S	Intravenous (not otherwise specified)	335.0 Days	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Sunconjunctival		Not Reported
Humira	S	Sunconjunctival		Not Reported
Humira	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported

Cortisone	S	Unknown	Not Reported
Apo-Folic Acid	S	Unknown	Not Reported
Apo-Folic Acid	S	Oral	Not Reported
Apo-Folic Acid	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Topicorte	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Sulfathalidine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Cortisone Acetate	S	Oral	Not Reported

Cortisone Acetate	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Hydrocortisone Acetate	S	Oral	Not Reported
Hydrocortisone Acetate	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Hydrocortisone Acetate	S	Cutaneous	Not Reported
Hydrocortisone Acetate	S	Oral	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Paracetamol	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

Hydroxychloroquine	S	Unknown	1 Every (Continued)	Not Reported
Hydroxychloroquine	S	Unknown	1 Every (Continued)	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Intracardiac		Not Reported
Phthalylsulfathiazole	S	Oral		Not Reported
Phthalylsulfathiazole	S	Oral		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Folic Acid	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown	1 Dosage	Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Topicort Lp	S	Unknown		Not Reported
Apo-Sulfasalazine	S	Oral		Not Reported
Cetirizine	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Golimumab	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Zyrtec [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Zyrtec [Cetirizine Hydrochloride]	S		Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Zyrtec-D	C		Not Reported
	Lisinopril	C		Not Reported
	Ibuprofen	C		Not Reported
	Atasol (Canada)	C		Not Reported
	Zyrtec-D	C		Not Reported
	Vitamin D3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	15585218	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ABBVIE-18K-028-2540122-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Disability; Drug Ineffective; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; Vascular Access Complication; White Blood Cell Count Increased	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Gp2013	Not Reported
	Rituximab	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous drip		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Abatacept	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	15654298	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018167420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Enbrel	S	Unknown	Unk	Amgen
	Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Asa	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram	Not Reported
	Gabapentin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	15674968	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573976-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free		Not Reported

Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure				Prefilled Syringes	
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Tocilizumab		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Anakinra		S	Subcutaneous	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Methotrexate		C	Oral	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	15676976	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573583-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Risedronate Sodium	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Plaquenil	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Actonel	S	Unknown		Not Reported
Apo Risedronate	S	Unknown		Not Reported
Apo Risedronate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Risedronate	S	Unknown		Not Reported
Apo Risedronate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Risedronic Acid	S	Unknown		Not Reported
Hydroxychloroquine	C			Not Reported
Hydroxychloroquine Sulfate	C			Not Reported
Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	16527868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555951-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia;	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution-Dosage Form		Not Reported

Rheumatoid Arthritis				(Form Of Administration)	
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	17928220	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3454131-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
	Humira			S	Sunconjunctival			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Topical			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Liver Injury; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S			Not Reported
	Topicort	S	Cutaneous		Not Reported
	Topicort	S	Topical		Not Reported
	Sarilumab	S	Unknown		Not Reported

Apo-Hydroxyquine	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac Diethylamine	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Oral	Not Reported
Cetirizine Hydrochloride	S		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S		Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Cortisone Acetate	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S		Not Reported
Plaquenil	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S		Not Reported
Salazopyrine	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S		Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Etanercept	S	Unknown	Not Reported
Winpred	S	Oral	Not Reported
Stelera	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported

	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Alendronate Sodium	S		Not Reported
	Cortisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S		Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Sulfathalidine	S		Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Zyrtec-D	S	Unknown	Not Reported
	Topicorten	S	Subcutaneous	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Atasol [Paracetamol]	C		Not Reported
	Ramipril	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18105674	EXPEDITED (15-DAY)		OT	CA-ACCORD-193607		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder;	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not	Intravenous		Not Reported

Thrombocytopenia			otherwise specified)	
	Rituximab	S	Unknown	Not Reported
	Advil	C		Not Reported
	Folic Acid	C		Not Reported
	Ketorolac	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Arava	S		Not Reported
	Methotrexate	S		Accord
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18237420	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017079		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Tocilizumab	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314078	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027057			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Humira			S	Unknown	40.0 Milligram, 1 Every 2 Weeks		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	5 Mg/Kg		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314079	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027069			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown			Not Reported
Erythromycin	C	Unknown			Not Reported
Methotrexate	C	Oral	Unk, 1 Every 1 Weeks		Not Reported
Morphine	C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314081	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027064			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Overdose; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Unknown	1000 Milligram		Not Reported
	Rituximab (Unknown)			S	Unknown	2000 Milligram, 1 Every 6 Months		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown	300 Milligram, 1 Every 6 Weeks		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Oral	10 Milligram, 1 Every 1 Weeks		Not Reported
	Prednisone			C	Oral	10 Milligram, 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314146	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027253			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Leflunomide	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Anakinra	S	Unknown			Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Azathioprine	S	Unknown			Not Reported
Azathioprine	S	Oral			Not Reported
Enbrel	S	Subcutaneous	25 Mg, 2 Every 1 Week		Not Reported
Etanercept	S	Subcutaneous	25 Mg, 2 Every 1 Week		Not Reported
Gold	S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314170	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027277			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314172	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA027124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Days		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, 4 Every 1 Weeks		Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown	60 Milligram, 2 Every 1 Days		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Ibuprofen			S	Oral	1 Every 1 Days		Not Reported

Ibuprofen	S	Oral	600 Milligram, 1 Every 1 Days	Not Reported
Infliximab	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	10 Milligram, 4 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	70 Milligram, 1 Every 1 Weeks	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Otezla	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Colchicine	C	Oral		Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314179	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027160			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314201	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027132			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral	25 Mg, 1 Every 1 Weeks		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Remicade		C	Unknown		Not Reported
	Xeljanz		C	Unknown	5 Mg, 1 Every 12 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314206	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027139			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Therapeutic Product Effect Decreased; Weight Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, 1 Every 1 Weeks		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314236	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027192			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	624 Mg		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Lasix [Furosemide]	C		Not Reported
	Methylprednisolone	C		Not Reported
	Naprosyn [Naproxen]	C		Not Reported
	Oxycontin	C		Not Reported
	Oxyneo	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314252	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027194			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314261	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027249			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314276	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027256			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314325	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027326			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Amlodipine Besilate			S	Oral	5.0 Milligram 1 Every 1 Days		Not Reported
	Asacol			S	Unknown	800.0 Milligram 3 Every 1 Days		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650.0 Milligram		Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported

Depo-Medrol	C	Intra-articular			Not Reported
Diphenhydramine	C	Oral	50.0 Milligram		Not Reported
Ebastine	C	Unknown			Not Reported
Ferrous Gluconate	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100.0 Milligram		Not Reported
Rosuvastatin Calcium	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Vitamin D3	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314374	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026744			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Atorvastatin Calcium			C				Not Reported
	Irbesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314421	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026564			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314441	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026632			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5.0 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown	500.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314505	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027430			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Unknown	1000.0 Milligram		Not Reported
	Enbrel			S	Unknown	25.0 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown	300.0 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314539	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027424			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Prednisone			S	Unknown			Not Reported

Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Sulfasalazine		S	Unknown	Not Reported
	Warfarin Sodium		S	Unknown	Not Reported
	Azathioprine		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Xarelto		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314561	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027443			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, 1 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314564	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027464			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Prescribed Underdose; Rheumatoid Arthritis;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab (Unknown)			S	Unknown	1 Gram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Weeks		Not Reported

Synovitis; Vomiting	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous	150 Milligram, 1 Every 1 Weeks	Not Reported
	Simponi	S	Unknown	50 Milligram, 1 Every 1 Months	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Milligram, 1 Every 1 Days	Not Reported
	Celebrex	C	Unknown	200 Milligram	Not Reported
	Naproxen	C	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
	Naproxen	C	Unknown	50 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314637	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown	162 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Azathioprine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314642	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026643			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314652	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026828			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Mg		Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314653	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026842			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Tofacitinib			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314654	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026873			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Hip Arthroplasty; Pulmonary	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral	25 Mg, 1/Week	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Actemra	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Remicade	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314657	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026819			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Naproxen			C	Unknown	500 Milligram, 2 Every 1 Days		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1		Not Reported

Days

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314742	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026808			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule	Rituximab (Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown	20 Mg, 1 Every 1 Day		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral	11 Mg, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314769	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027008			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314899	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027417			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown	1 Every 24 Hours		Not Reported
	Prednisone			C	Oral	10 Mg, 1 Every 24 Hours		Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314927	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026874			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug	Rituximab (Unknown)			S	Intravenous drip	2000 Mg		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported

Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Other	Unk	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous	750 Mg	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314955	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027498			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18314990	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027502			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	1000 Milligram, 1 Every 12 Hours	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every 1 Months	Not Reported
	Actemra	S	Unknown	360 Milligram	Not Reported
	Actemra	S	Unknown	360 Milligram	Not Reported
	Actemra	S	Unknown	2.68 Milligram, 1 Every 4 Weeks	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, 1 Every 1 Weeks	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	12 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	70 Milligram, 1 Every 1	Not Reported

			Weeks	
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	12.0 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 2 Weeks	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Weeks	Not Reported
Myochrysine	S	Parenteral	50 Milligram, 1 Every 1 Months	Not Reported
Orencia	S	Unknown	780 Milligram, 1 Every 1 Weeks	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Ciclosporin	C			Not Reported
Prednisone	C			Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315207	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026198			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25.0 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300.0 Milligram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Xeljanz			S	Oral	5.0 Milligram		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315222	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026369			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Rituximab (Unknown)	S	Intravenous drip	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315242	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026388			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine[Cetirizine Hydrochloride]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315245	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA027519			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	Unk, 1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315255	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026203			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported

Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Apo-Leflunomide	S	Unknown	20.0 Mg 1 Every 1 Day	Not Reported
	Arava	S	Unknown	20.0 Mg 1 Every 1 Day	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	200.0 Mg, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg, 1 Every 1 Day	Not Reported
	Methotrexate	S	Unknown	20.0 Mg	Not Reported
	Methotrexate	S	Unknown	20.0 Mg	Not Reported
	Methotrexate Sodium	S	Unknown	20.0 Mg, 1 Every 1 Week	Not Reported
	Methotrexate Sodium	S	Unknown	20.0 Mg, 1 Every 1 Day	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200.0 Mg, 1 Every 1 Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral	5.0 Mg, 2 Every 1 Day	Not Reported
	Acetaminophen;Caffeine	C	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported
	Advil [Mefenamic Acid]	C	Unknown		Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Ketorolac	C	Unknown		Not Reported
	Leflunomide	C	Unknown	20.0 Mg	Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315256	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA026204			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Rituximab (Unknown)			S	Intravenous (not			Not Reported

Adverse Event; Arthropathy; Breast Cancer Stage Iii; Condition Aggravated; Depression; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Hand Deformity; Infection; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Off Label Use; Ovarian Cancer; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Unevaluable Event; Urticaria			otherwise specified)		
	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Cefazolin	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous	400.0 Milligram, 1 Every 2 Weeks	Not Reported
	Certolizumab Pegol	S	Subcutaneous	200.0 Milligram, 1 Every 2 Weeks	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 1 Every 1 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Amlodipine	C	Unknown		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Viread	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315263	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA026337			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	162.0 Milligram		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown	160.0 Milligram		Not Reported
	Azathioprine			C	Subcutaneous	50.0 Milligram, 1 Every 1 Day		Not Reported
	Imuran [Azathioprine]			C	Subcutaneous	50.0 Milligram, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831069		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease;	Methotrexate			S	Unknown			Barr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Bactrim		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315272	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026344			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Actemra			S	Unknown	8 Mg		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported

	Elavil [Allopurinol]	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315279	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831773		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Diovan			C				Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C				Not Reported
	Sertraline			C	Unknown			Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315280	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1831764		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Enbrel	S	Unknown	Not Reported
	Erelzi	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315288	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832406		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Acetaminophen	C			Not Reported
	Codeine	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315297	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026214			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous	125 Mg, 1 Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	Unk, 1 Every 1 Week		Not Reported
	Methotrexate			S	Oral	25 Mg, 1 Every 1 Week		Not Reported
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Oral	200 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315307	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026217			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315321	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026400			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20.0 Milligram, 1 Every 1 Day		Not Reported

Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Somnolence; Visual Impairment	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Week	Not Reported
	Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 1 Every 12 Hours	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000.0 Milligram	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25.0 Milligram, 1 Every 1 Week	Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315324	EXPEDITED (15-DAY)		OT	CA-ACCORD-202622		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Mellitus; Vomiting	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Leflunomide		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315325	EXPEDITED (15-DAY)		OT	CA-ACCORD-202628		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S		1 Every 1 Weeks		Accord
	Hydroxychloroquine			S				Not Reported
	Mycophenolic Acid			S				Accord
	Actemra			S				Not Reported
	Amoxicillin/Clavulanic Acid			S				Not Reported
	Azathioprine			S				Not Reported
	Ciprofloxacin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Prednisone			C				Not Reported
	Tridural			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315328	EXPEDITED (15-DAY)		OT	CA-ACCORD-202632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site	Hydroxychloroquine			S		1 Every 24 Hours		Not Reported

Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Accord
	Azathioprine		S			Not Reported
	Actemra		S	Subcutaneous	1 Every 1 Weeks	Not Reported
	Ciclosporin		S			Not Reported
	Enbrel		S			Not Reported
	Gold		S			Not Reported
	Kevzara		S	Subcutaneous		Not Reported
	Leflunomide		S	Oral		Not Reported
	Sodium Aurothiomalate		S	Parenteral		Not Reported
	Sulfasalazine		S			Not Reported
	Hydroxychloroquine		S	Oral	1 Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315336	EXPEDITED (15-DAY)		OT	CA-ACCORD-202771		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Oral			Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315338	EXPEDITED (15-DAY)		OT	CA-ACCORD-202787		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib			S				Not Reported

Diovan	C		Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C		Not Reported
Sertraline	C		Not Reported
Valtrex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315340	EXPEDITED (15-DAY)		OT	CA-ACCORD-202784		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315349	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832378		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Intravenous (not			Not Reported

			otherwise specified)		
	Xeljanz	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Esomeprazole	C	Unknown	40 Milligram Daily;	Not Reported
	Esomeprazole	C	Unknown	40 Milligram Daily;	Not Reported
	Lumigan Rc	C	Ophthalmic		Not Reported
	Sulfasalazine	C	Unknown	2000 Milligram Daily;	Not Reported
	Trazodone	C	Unknown	200 Milligram Daily;	Not Reported
	Tylenol	C	Unknown		Not Reported
	Tylenol Extra Strength	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315354	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027227			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sciatica	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	7.0 Mg, 1 Every 1 Day		Not Reported
	Apo-Ramipril			S	Unknown	Unk, 1 Every 1 Day		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg, 1 Every 1 Day		Not Reported
	Levothyroxine			S	Unknown	Unk, 1 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Mg, 1 Every 1 Week		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)			
	Acetaminophen;Caffeine;Dihydrocodeine Bitartrate	C				Not Reported
	Acetaminophen;Codeine	C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic	Unk, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate	C		400.0 Mg, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315367	EXPEDITED (15-DAY)		OT	CA-ACCORD-202566		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Hydroxychloroquine			S	Unknown	Also Received 200.0 Mg		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	1 Every 1 Days		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315368	EXPEDITED (15-DAY)		OT	CA-ACCORD-202561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zyrtec-D			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported

Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Topicorten	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Every 1 Days	Not Reported
	Stelara	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Reactine (Cetirizine)	S	Unknown		Not Reported
	Pseudoephedrine	S	Unknown		Not Reported
	Plaquenil	S		1 Every 1 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Folic Acid	S	Oral	Also Received 5.0 Mg	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Cortisone	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cetirizine	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315369	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027229			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315379	EXPEDITED (15-DAY)		OT	CA-ACCORD-202571			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Fosamax	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315380	EXPEDITED (15-DAY)		OT	CA-ACCORD-202569		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Esomeprazole			S	Unknown			Not Reported
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Xeljanz			S	Oral	2 Every 1 Days		Not Reported
	Thiamine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Nicotinamide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Kevzara			S	Subcutaneous	1 Every 2 Weeks, Also Received 20.0 And 20.0 Mg		Not Reported
	Gold/Gold Keratinate/Gold Monosulfide/Gold Trisulfide			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Esomeprazole	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Ciclosporin	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Actemra	S	Subcutaneous	1 Every 1 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315384	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA026383			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram, 1 Every 1 Days		Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral	5.0 Milligram,2 Every 1 Days	Not Reported
Atorvastatin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Bisoprolol	C	Unknown		Not Reported
Digoxin	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Furosemide [Furosemide Sodium]	C	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Hydroxychloroquine	C	Unknown	200.0 Milligram,1 Every 2 Weeks	Not Reported
Hydroxychloroquine	C	Unknown	200.0 Milligram,2 Every 1 Days	Not Reported
Leflunomide	C	Unknown	20.0 Milligram,1 Every 1 Days	Not Reported
Lyrica	C	Unknown	75.0 Milligram,1 Every 1 Days	Not Reported
Naproxen	C	Unknown	500.0 Milligram,1 Every 1 Days	Not Reported
Nifedipine	C	Unknown		Not Reported
Palafer	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Prednisone	C	Unknown	5.0 Milligram,1 Every 1	Not Reported

				Days	
	Prednisone	C	Unknown	10.0 Milligram,2 Every 1 Days	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown		Not Reported
	Tocilizumab	C	Unknown		Not Reported
	Toloxin [Digoxin]	C	Unknown		Not Reported
	Trazodone	C	Unknown	50.0 Milligram 1 Every 1 Days	Not Reported
	Valsartan	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xarelto	C	Unknown		Not Reported
	Zinc Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315386	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026391			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	3000 Mg, 1 Every 1 Days		Not Reported
	Esomeprazole			C	Unknown	40 Mg, 1 Every 1 Days		Not Reported

	Esomeprazole Sodium	C	Unknown		Not Reported
	Lumigan Rc	C	Ophthalmic	Unk, 1 Every 1 Days	Not Reported
	Lyrica	C	Unknown	150 Mg	Not Reported
	Sulfasalazin	C	Unknown	1000 Mg, 2 Every 1 Days	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown	10 Mg, 1 Every 1 Days	Not Reported
	Trazodone	C	Unknown	200 Mg, 1 Every 1 Days	Not Reported
	Valsartan	C	Unknown	Unk, 1 Every 1 Days	Not Reported
	Wellbutrin	C	Unknown	300 Mg, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315405	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027158			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use, Pre-Filled Syringe		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, 1/Week		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported

Methotrexate	C	Unknown	Unk, 1/Week		Not Reported
Meloxicam	C	Unknown			Not Reported
Leflunomide	C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315429	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831206			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315443	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831841		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Migraine; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intracavernous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315444	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832347		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315467	EXPEDITED (15-DAY)		OT	CA-ACCORD-202662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S				Not Reported
	Alendronic Acid			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil			S		1 Every 1 Days		Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	1 Every 12 Hours		Not Reported
	Tofacitinib			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315475	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027268			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315481	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831745		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Loss Of Personal Independence In	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315484	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1831838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315485	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Ciclosporin			S	Unknown			Ivax

Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315495	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831851			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315626	EXPEDITED (15-DAY)		OT	NVSC2020ES250898		37 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Failure	Azithromycin			S	Unknown	250 Mg, Qd		Novartis
	Azithromycin			S	Unknown	250 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Q12h (Trade Name: Dolquine)		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Q12h (Trade Name: Dolquine)		Not Reported
	Methylprednisolone			S	Unknown	60 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	60 Mg, Qd		Not Reported
	Kaletra			S	Unknown	500 Mg (400/100 Mg), Q12h		Not Reported
	Kaletra			S	Unknown	500 Mg (400/100 Mg), Q12h		Not Reported
	Simvastatine			C	Oral	20 Mg, Unknown		Not Reported
	Omeprazol			C	Oral	20 Mg, Unknown		Not Reported
	Hidroferol			C	Unknown	Unk Unk, Qmo		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315696	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832018			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315698	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Alendronate Sodium			S	Oral			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315748	EXPEDITED (15-DAY)		OT	NVSC2020CA253494			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Ascorbic Acid			S	Unknown	Unk		Not Reported
	Calcium			S	Unknown	Unk		Novartis
	Colecalciferol			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Intracardiac	Unk		Not Reported
	Alendronic Acid			S	Intracardiac	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Sulfasalazine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Calcium Glubionate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Intracardiac	Unk	Not Reported
Tocilizumab	S	Intracardiac	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Fosamax	S	Intracardiac	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Actemra	S	Intracardiac	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Calcium Gluconate	C	Unknown	Unk	Not Reported
Calcium Gluconate	C	Unknown	Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Ramipril	C	Unknown	Unk	Not Reported

	Ramipril	C	Unknown	Unk	Not Reported
	Quetiapine Fumarate	C	Unknown	Unk	Not Reported
	Quetiapine Fumarate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315761	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA249029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	200 Mg		Not Reported
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sarilumab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Unknown	Unk		Not Reported
Tofacitinib	S	Unknown	5 Mg		Not Reported
Xeljanz	S	Unknown	5 Mg		Not Reported
Phthalylsulfathiazole	S	Oral	1000 Mg		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315765	EXPEDITED (15-DAY)		OT	NVSC2020CA252451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cetirizine Hydrochloride			S	Unknown	20 Mg		Novartis
	Hydrocortisone			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	1 Dosage Form		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	20 Mg		Not Reported

	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	90 Mg	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315788	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026272			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25.0 Milligram 2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram, 1 Every 2 Weeks		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Weeks	Not Reported
	Leflunomide	S	Unknown	20.0 Milligram 1 Every 1 Days	Not Reported
	Methotrexate	S	Unknown	20.0 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	15.0 Milligram 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram 1 Every 6 Weeks	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram 1 Every 6 Weeks	Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315790	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA026286			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1.0 Gram		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	162.0 Milligram, 1 Every 2 Weeks		Not Reported
	Anakinra			S	Subcutaneous	100.0 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral	20.0 Milligram, 1 Every 1 Day		Not Reported
	Azathioprine			S	Oral	200.0 Milligram, 1 Every 1 Day		Not Reported
	Azathioprine			S				Not Reported

Azathioprine	S	Unknown		Not Reported
Azathioprine	S			Not Reported
Azathioprine Sodium	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	50.0 Milligram, 1 Every 1 Week	Not Reported
Etanercept	S	Subcutaneous	25.0 Milligram, 2 Every 1 Week	Not Reported
Gold	S	Intramuscular		Not Reported
Humira	S	Subcutaneous	40.0 Milligram, 1 Every 2 Weeks	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Infliximab	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Unknown	25.0 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S			Not Reported
Orencia	S	Subcutaneous	125.0 Milligram, 1 Every 1 Week	Not Reported
Penicillamine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram	Not Reported
Simponi	S	Subcutaneous	50.0 Milligram, 1 Every 1 Month	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
Docusate Sodium	C	Oral	100.0 Milligram, 1 Every 1 Day	Not Reported
Doxycycline	C	Oral		Not Reported
Elavil [Allopurinol]	C	Unknown		Not Reported
Prednisone	C	Oral	8.0 Milligram, 1 Every 1	Not Reported

				Day	
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Oral	1.5 Gram, 2 Every 1 Day	Not Reported
	Tobramycin	C	Unknown	0.3 Percent, 4 Every 1 Day	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315791	EXPEDITED (15-DAY)		OT	NVSC2020CA254984			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cetirizine Hydrochloride			S	Unknown	25 Mg		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Hydrocortisone Acetate			S				Not Reported
	Alendronate Sodium Trihydrate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported

Cortisone Acetate	S	Oral	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Desoximetasone	S	Oral	Unk		Not Reported
Desoximetasone	S	Subcutaneous	Unk		Not Reported
Desoximetasone	S	Unknown	Unk		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	5 Mg		Not Reported
Paracetamol	C	Unknown	Unk		Not Reported
Codeine Phosphate	C	Unknown	Unk		Not Reported
Caffeine Citrate	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315792	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026301			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Day		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	5 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1/Week		Not Reported

System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	25 Mg	Not Reported
	Arava	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315805	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026495			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315812	EXPEDITED (15-DAY)		HO, LT	CA-CELLTRION INC.-2020CA027438			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased;	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not	Unk		Not Reported

Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria			otherwise specified)		
	Rituximab (Unknown)	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S			Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S			Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315813	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026532			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	200 Milligram, 1 Every 1 Days		Not Reported

	Leflunomide	S	Unknown	15 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 6 Weeks	Not Reported
	Sulfasalazine	C	Unknown	1 Gram, 2 Every 1 Days	Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315814	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026538			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315827	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026708			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Diclofenac Sodium;Misoprostol			S	Unknown	Unk		Not Reported
	Diclofenac Sodium;Misoprostol			S	Unknown	50 Milligram, 2 Every 1 Days		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported

	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	7.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	7.5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arthrotec	C	Unknown	50 Milligram, 2 Every 1 Days	Not Reported
	Gold	C			Not Reported
	Imuran [Azathioprine]	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315830	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026754			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label	Rituximab (Unknown)			S	Intravenous drip	1000 Milligram, 2 Every 1 Day		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 1 Week		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, 1 Every 1 Week		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Unknown	12 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
	Orencia	S	Unknown	780 Milligram, 1 Every 1 Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Day	Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18315831	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027012			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Rituximab (Unknown)			S	Intravenous (not			Not Reported

Intolerance; Non-Hodgkin'S Lymphoma			otherwise specified)			
	Apo-Azathioprine	S	Unknown	100.0 Milligram		Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	100.0 Milligram		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Minocycline	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	5.0 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18321872	DIRECT		DE, OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue; Respiratory Failure	Lopinavir-Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	15396329	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20180911207		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Tylenol			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Paracetamol	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported

Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Actemra	S	Subcutaneous	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Actemra	S		Not Reported
Apo-Acetaminophen	S	Unknown	Not Reported
Apo-Acetaminophen	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Leflunomide	S	Oral	Not Reported

	Doxycycline Hyclate	S	Unknown	Not Reported
	Leflunomide	C	Oral	Not Reported
	Leflunomide	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Tylenol W/Codeine No. 3	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Celecoxib	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	16193459	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036681		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache;	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Methotrexate			S	Unknown	15 Milligram Daily;		Barr
	Methotrexate			S	Endocervical	25 Milligram Daily;		Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr

Infection; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Leflunomide	S	Oral	Barr
	Leflunomide	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine /00072603	S	Unknown	Not Reported
	Hydroxychloroquine /00072603	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	16890816	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2951359-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18273980	EXPEDITED (15-DAY)		DE, OT	CA-JNJFOC-20200927354		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Death Neonatal; Drug Ineffective; Glossodynia; Hypersensitivity; Malaise; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Failure	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Acetaminophen	S	Transplacental	Not Reported
	Benadryl /00000402/	S	Transplacental	Not Reported
	Solu-Medrol	S	Transplacental	Not Reported
	Salazopyrin	C	Oral	Not Reported

FDA Adverse Event Reporting System
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Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18301592	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026274			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Inflammation; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, 1 Every 4 Weeks		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg		Not Reported
	Arava			S	Unknown	20 Mg, 1 Every 1 Days		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, 1 Every 1 Days		Not Reported
	Methotrexate			S	Oral	15 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Subcutaneous	125 Mg, 1 Every 1 Week		Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg,2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Qd		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315852	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026848			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Days		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 1 Months		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Months		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, 1 Every 1 Weeks		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, 1 Every 1 Weeks		Not Reported

Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Weeks		Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Months		Not Reported
Orencia	S	Unknown	780 Milligram, 1 Every 1 Weeks		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Days		Not Reported
Prednisone	C	Unknown	10 Milligram, 1 Every 1 Days		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315859	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026926			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315872	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026686			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315873	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026687			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg		Not Reported
	Arava			S	Unknown	10 Milligram, 1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not	750 Milligram, 1 Every 1		Not Reported

Peripheral Swelling; Rash; Syncope; Urticaria			otherwise specified)	Months		
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	50 Milligram, 1 Every 1 Months		Not Reported
	Prednisone	C	Unknown	50 Milligram, 1 Every 1 Days		Not Reported
	Prevacid	C	Unknown			Not Reported
	Xeljanz	C	Oral	50 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315874	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027016			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315875	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026960			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Rituximab (Unknown)			S	Intravenous (not	Unk		Not Reported

Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis			otherwise specified)			
	Apo-Azathioprine	S	Unknown	100.0 Milligram		Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	25.0 Milligram		Not Reported
	Minocycline Hydrochloride	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315891	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027335			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	1 Every 1 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	22.5 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Parenteral	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported

Azathioprine	C	Unknown	1 Every 1 Days		Not Reported
Ciclosporin	C	Unknown			Not Reported
Minocycline	C	Unknown			Not Reported
Penicillamine	C	Unknown			Not Reported
Prednisone	C	Unknown	6 Mg, 2 Every 1 Days		Not Reported
Tocilizumab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315895	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026753			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid (1 Every 12 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315900	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026843			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint	Rituximab (Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Azathioprine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Simponi		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Prednisone		C	Unknown	10.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315901	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027186			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Calcium			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folinic Acid			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315912	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026904			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown	12.5 Milligram, 1 Every 1 Days		Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315922	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA026890			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Mg		Not Reported
	Acetaminophen			S	Oral	65.0 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520.0 Milligram		Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Dilaudid	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	15.5 Milligram	Not Reported
	Hydromorphone Hydrochloride	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300.0 Milligram, 1 Every 24 Hours	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Prednisone	S	Unknown	7.5 Milligram	Not Reported
	Alendronate Sodium;Vitamin D Nos	C	Unknown		Not Reported
	Humira	C			Not Reported
	Hydrocortisone	C			Not Reported
	Hyzaar	C	Unknown		Not Reported
	Methylprednisolone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315923	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026921			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Form, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous			Not Reported
Lyrica	C	Oral			Not Reported
Prednisone	C	Oral			Not Reported
Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315943	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026321			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin Potassium]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315944	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026329			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, 2 Every 1 Days		Not Reported
	Cephalexin [Cefalexin]			C	Unknown	500.0 Milligram, 3 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315946	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026351			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25.0 Milligram, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram,1 Every 2		Not Reported

				Weeks	
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram	Not Reported
	Leflunomide	S	Unknown	20.0 Milligram, 1 Every 1 Day	Not Reported
	Methotrexate	S	Unknown	20.0 Milligram, 1 Every 1 Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram, 1 Every 6 Weeks	Not Reported
	Bupropion	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315948	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026405			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

	Prednisone			C	Unknown	5 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315949	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026376			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315951	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026377			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased	Rituximab (Unknown)	S	Unknown		Not Reported
	Actemra	S	Unknown	162 Mg	Not Reported
	Cimzia	S	Unknown	Single-Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Azathioprine	C	Unknown	50 Mg, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315964	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026970			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500.0 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unk		Not Reported

Arava	S	Unknown	Unk		Not Reported
Actemra	S	Subcutaneous	Unk		Not Reported
Folic Acid	S	Unknown	5.0 Milligram		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315969	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026996			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab (Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	100.0 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315973	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027013			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Etanercept	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300.0 Milligram 1 Every 24 Hours	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20.0 Milligram 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	65.0 Milligram 1 Every 1 Weeks	Not Reported
Methotrexate	S	Oral	65.0 Milligram 1 Every 1 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315975	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027009			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram	Not Reported
Xeljanz	C	Unknown	5 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315976	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027011			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	20.0 Mg, Qd (1 Every 1 Days)		Not Reported
	Enbrel			S	Unknown	50.0 Mg, 1/Week (1 Every 1 Week)		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Q2weeks (1 Every 2 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Mg, Bid (2 Every 1 Days)		Not Reported
	Methotrexate			S	Oral	175.0 Mg, 1/Week (1 Every 1 Week)		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315977	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027010			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, 1 Every 1 Days		Not Reported

Abnormal; Rheumatoid Arthritis; Synovitis	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Every 24 Hours	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram	Not Reported
	Risedronate Sodium	S	Oral	35 Milligram, 1 Every 1 Weeks	Not Reported
	Risedronate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18315984	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027044			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown	Unk, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316014	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027063			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Rituximab (Unknown)	S	Intravenous drip		Not Reported
	Celebrex	S	Oral	200.0 Milligram, 1 Every 12 Hours	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500.0 Milligram, 1 Every 12 Hours	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, 1 Every 12 Hours	Not Reported
	Arava	C	Unknown	20.0 Milligram, 1 Every 1 Days	Not Reported
	Arava	C	Unknown	20.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316021	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027154			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, 1/Week		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, 1/Week		Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316022	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027157			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	400.0 Milligram 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200.0 Milligram 1 Every 2 Weeks		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram 1 Every 2 Weeks		Not Reported
	Leflunomide			S	Oral	10.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported

	Viread			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316023	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027162			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500.0 Mg		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5.0 Mg, 2 Every 1 Day		Not Reported
	Xeljanz			S	Oral	10.0 Mg, 2 Every 1 Day		Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous	100.0 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316056	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027294			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Rituximab (Unknown)	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50.0 Milligram, 1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir	C	Unknown		Not Reported
	Tenofovir Disoproxil	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316071	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027171			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported

Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Certolizumab Pegol	S	Subcutaneous	200 Milligram, 1 Every 2 Weeks	Not Reported
	Certolizumab Pegol	S	Subcutaneous	400 Milligram, 1 Every 2 Weeks	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Amlodipine	C		Unk	Not Reported
	Arava	C		Unk	Not Reported
	Benadryl	C	Unknown	Unk	Not Reported
	Naproxen	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Viread	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316072	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027173			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Arava			S	Unknown	20.0 Milligram		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316075	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027185			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316076	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027175			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure	Rituximab (Unknown)			S	Intravenous drip	1000 Milligram		Not Reported

Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate	S	Oral	1 Every 1 Days	Not Reported
	Amlodipine Besilate	S	Oral	5 Milligram, 1 Every 1 Days	Not Reported
	Asacol	S	Unknown	800 Milligram, 3 Every 2 Days	Not Reported
	Diamicron	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Gliclazide	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Ebastine	C			Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Methylprednisolone Acetate	C	Intra-articular		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316084	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027275			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituximab (Unknown)	S	Intravenous drip			Not Reported
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 1 Every 12 Hours		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Arthrotec	C				Not Reported
	Azathioprine	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316085	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027271			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	C	Unknown	500 Mg, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316229	EXPEDITED (15-DAY)		OT	NVSC2020ES258434		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	400 Mg, Bid (First Day)		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Lopinavir/Ritonavir			C	Unknown	Unk Unk, Bid (200 Mg/50 Mg)		Not Reported
	Teicoplanin			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316270	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA254995			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal	Methotrexate Sodium			S	Oral	20 Mg		Novartis
	Prednisone			S	Oral	7.5 Mg		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported

Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pruritus	Cetirizine Hydrochloride	S	Intracardiac	10 Mg	Not Reported
	Chlorhexidine Gluconate	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tofacitinib	S	Unknown	10 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Oxycodone + Apap	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Mg	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Mg	Not Reported
	Isopropanol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316271	EXPEDITED (15-DAY)		OT	NVSC2020CA253931			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product	Folic Acid			S	Oral	5 Mg		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1 Df (Dosage Form)		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported

Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Alendronic Acid	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Codeine Phosphate	C	Unknown	Unk	Not Reported
	Caffeine Citrate	C	Unknown	Unk	Not Reported

	Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316272	EXPEDITED (15-DAY)		OT	NVSC2020US259416		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis
	Methotrexate			C	Unknown	Unk		Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported
	Abatacept			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316276	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1831835		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress;	Methotrexate			S	Subcutaneous			Barr
	Indometacin			S	Unknown			Actavis
	Indometacin			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Indocid	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Cymbalta	C	Oral	30 Milligram Daily;	Not Reported
	Folic Acid	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316279	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832359		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Soft Tissue Disorder;	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported

Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316321	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis	Indometacin			S	Oral	150 Milligram Daily;		Actavis
	Indometacin			S	Oral	200 Milligram Daily;		Actavis
	Indometacin			S	Oral			Actavis
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Indomethacin [Indometacin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316322	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1831811		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831846			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Eye Disorder; Hip Surgery; Hypertension; Pneumonia; Post Procedural Infection; Restless Legs Syndrome	Methotrexate			S	Unknown			Barr
	Minocycline			S	Unknown			Actavis
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rofact [Rifampicin]			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Quetiapine			C				Not Reported
	Trazodone			C				Not Reported
	Chlormezanone			C				Not Reported
	Colchicine			C				Not Reported
	Dexilant			C				Not Reported
	Diclofenac Sodium			C				Not Reported
	Hydromorph Contin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316328	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832031		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316333	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832440		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort;	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Acetaminophen			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Prednisone	S	Unknown		Actavis
	Stelara	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported

Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Oral	400 Milligram Daily;	Not Reported
Reactine (Cetirizine)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Subcutaneous	2 Gram Daily;	Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
Salazopyrin	C			Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316337	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831783		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18316347	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831795		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Oral	1000 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Baclofen			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Sulfadiazine			S	Unknown			Not Reported

	Xeljanz			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18321821	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Heart Rate Increased; Product Use Issue	Hydroxychloroquine			S				Not Reported
	Darunavir-Cobicstat			S				Not Reported
	Colchicine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18322480	DIRECT					40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Level Increased; Intentional Product Use Issue; Nausea; Vomiting	Lopinavir-Ritonavir			S		Other Dose:400/100mg;	2 DAY	Not Reported
	Hydroxychloroquine			S			2 DAY	Not Reported
	Ceftriaxone			S			4 DAY	Not Reported
	Darunavir-Cobicstat			S		Other Dose:800/150mg;	2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18322489	DIRECT		OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Guillain-Barre Syndrome; Intentional Product Use Issue	Hydroxychloroquine			S				Not Reported
	Lopinavir-Ritonavir			S				Not Reported
	Azithromycin			S				Not Reported
	Immunoglobulins, Intravenous			S	Intravenous (not otherwise specified)	Other Dose:0.4g/Kg/;	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	11326249	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015075697		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Amgen
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Amgen
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	500 Milligram, Cyclical	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4mo	Not Reported
	Orencia	S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	12.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Kineret	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported

Apo-Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
Methotrexate Sodium	S	Unknown	12.5 Milligram		Not Reported
Methotrexate Sodium	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	11489777	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015275679		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	12769848	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia	S			Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Arava	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Cannabis Sativa	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S			Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk, Q12h	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported

Rituximab;Urelumab	C	Unknown	Unk		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Kineret	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk, Qd		Not Reported
Rituximab	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	Unk Unk, Bid		Not Reported
Xeljanz	C	Unknown	5 Milligram		Not Reported
Urelumab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	13074395	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2791		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown	On High Doses For		Not Reported

				Several Years	
	Apo-Warfarin	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Warfarin	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Amitriptyline	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	13519599	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038053		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown	4 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Methotrexate	C	Unknown	0.8 Ml, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	13566531	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017031203		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	13929686	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2700		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	Cyclical		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Apo Leflunomide	S	Oral		Not Reported
Apo Leflunomide	S	Unknown		Not Reported
Apo Leflunomide	S	Unknown		Not Reported
Humira	S	Subcutaneous	Cyclic	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Kineret	S	Subcutaneous		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Unknown		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Cyclic	Not Reported
Orencia	S	Unknown	Cyclical	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported

	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	14222196	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP007826		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Prednisone			S	Unknown	7 Mg, Qd		Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S				Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Celecoxib			S	Unknown	Unk		Apotex
	Celecoxib			S				Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Mg, Unk		Not Reported
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.Wk.		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Ml, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	1 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	25 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Q.M.T.	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Q.M.T.	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Altace	C	Unknown	5 Milligram	Not Reported
Altace	C	Unknown	10 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C	Unknown	300 Milligram	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Qd	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram	Not Reported
Cipralex [Escitalopram]	C	Unknown	20 Milligram	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	20 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	0.625 Milligram	Not Reported
Cymbalta	C	Unknown	60 Milligram	Not Reported
Cymbalta	C	Unknown	30 Milligram, Qid	Not Reported
Cymbalta	C	Unknown	120 Milligram, Qd	Not Reported
Escitalopram	C	Unknown	10 Milligram	Not Reported
Estrace	C	Unknown	0.5 Milligram	Not Reported
Hydrochlorothiazide	C	Unknown	12.5 Milligram	Not Reported
Hydromorphone Hcl	C	Oral	30 Milligram, Bid	Not Reported

Hydromorphone Hcl	C	Oral	3 Milligram, Bid		Not Reported
Mupirocin	C	Topical	Unk		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	20 Milligram, Qd		Not Reported
Shark Liver Oil	C	Unknown	Unk		Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Milligram		Not Reported
Taro-Mupirocin	C	Topical	Unk		Not Reported
Tramacet	C	Oral	Unk		Not Reported
Tramadol Hydrochloride	C	Unknown	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	14634857	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019446		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Inflammation; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	1 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported

Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Urticaria	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Q4wk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	14921431	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044618			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	4 Dosage Form, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	15259069	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0134		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Arthritis; Back Pain; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Herpes Zoster; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Oral Pain; Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2 Times/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Cyclic	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Cyclic	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not		Not Reported

		otherwise specified)		
Xeljanz	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Doxycycline Hyclate	S	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Day 1 &15	Not Reported
Rituxan	C	Intravenous (not otherwise specified)		Not Reported
Ativan	C	Unknown	At Bedtime	Not Reported
Ativan	C	Unknown		Not Reported
Ativan	C	Unknown		Not Reported
Cortisone	C	Intramuscular		Not Reported

Cortisone	C	Intra-articular		Not Reported
Darifenacin Hydrobromide	C	Unknown	As Needed.	Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Benadryl	C	Unknown	As Necessary	Not Reported
Benadryl	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Furosemide	C	Unknown	3x/Week	Not Reported
Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Pantoloc	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Vagifem	C	Vaginal		Not Reported
Vagifem	C	Unknown		Not Reported
Leflunomide	C	Unknown		Not Reported
Abatacept	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lasix	C	Unknown	40 Mg, 3x/Day	Not Reported
Lasix	C	Unknown		Not Reported
Enablex	C	Unknown	As Needed	Not Reported
Enablex	C	Unknown		Not Reported

Desoximetasone	C	Oral		Not Reported
Desoximetasone	C	Intramuscular		Not Reported
Desoximetasone	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown		Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Diphenhydramine	C	Unknown		Not Reported
Diphenhydramine	C	Unknown		Not Reported
Dexamethasone	C	Unknown		Not Reported
Dexamethasone	C	Oral		Not Reported
Darifenacin	C	Unknown		Not Reported
Dyclone	C	Unknown		Not Reported
Kenalog	C	Intra-articular		Not Reported
Kenalog	C	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported
Dyclonine Hydrochloride	C	Unknown		Not Reported
Anakinra	C	Unknown		Not Reported
Laxisoft	C	Unknown		Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported
Benadryl	C	Unknown	As Needed.	Not Reported

Benadryl	C	Unknown			Not Reported
Synthroid	C	Unknown			Not Reported
Lasix	C	Unknown			Not Reported
Lasix	C	Unknown			Not Reported
Orphenadrine [Orphenadrine Hydrochloride]	C				Not Reported
Simponi	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Methotrexate	C	Vaginal	4 Times/Week		Not Reported
Methotrexate	C	Unknown	4 Times/Wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	15311145	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2016AP014163		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Off Label Use; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood	Naproxen			S	Oral	100 Mg, Qd		Apotex
	Naproxen			S	Oral	500 Mg, Bid		Apotex
	Naproxen			S	Oral	1000 Mg, Qd		Apotex
	Folic Acid			S	Unknown	5 Milligram, B.I.Wk. (Twice In A Week)		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Bid		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Q.O.Wk.		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	40 Mg, Unknown		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex

Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine	S	Unknown	40 Mg, Qd	Apotex
	Pantoprazole	S	Unknown	40 Mg, Qd	Apotex
	Leflunomide	S	Oral	20 Mg, Qd	Apotex
	Prednisone	S	Unknown	Unk	Not Reported
	Atenolol	S	Unknown	25 Mg, Qd	Apotex
	Celecoxib	S	Unknown	Unk	Apotex
	Sulfasalazin	S	Oral	500 Mg, Bid	Not Reported
	Sulfasalazin	S	Oral	1000 Mg, Bid	Not Reported
	Co Atenolol	S	Unknown	25 Mg, Qd	Not Reported
	Co Atenolol	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, 1 Every 2 Weeks	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Q.O.Wk.	Not Reported
	Palafer Cf	S	Unknown	Unk Unk, Qd	Not Reported
	Pantoloc /01263204/	S	Unknown	40 Mg, Qd	Not Reported
	Pantoloc /01263204/	S			Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Naprosyn /00256201/	S	Oral	500 Mg, Bid	Not Reported
	Naprosyn /00256201/	S	Oral	1000 Mg, Qd	Not Reported
	Naprosyn /00256201/	S	Oral	100 Mg, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	40 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	Unk, Unknown	Not Reported
	Humira	S	Subcutaneous	Unk, Unknown	Not Reported
	Orencia	S	Unknown	Unk Unk, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Adalimumab	S	Subcutaneous	Unk, Unknown	Not Reported
Abatacept	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk, Unknown	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Mg, Qd	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk Unk, Q.O.Wk.	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	20 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Oral	25 Milligram, B.I.Wk.	Not Reported
Methotrexate	S	Unknown	25 Milligram, Q.O.Wk.	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Teva Pantoprazole	S	Unknown	40 Mg, Qd	Not Reported
Vitamin C /00008001/	S	Unknown	Unk, Qd	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Q.O.Wk.	Not Reported
Celebrex	C	Oral	200 Mg, Qd	Not Reported
Celebrex	C	Unknown	Unk, Qd	Not Reported
Prednisone	C	Intracardiac	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk Unk, Q.O.Wk.	Not Reported
Celecoxib	C	Oral	200 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	15400294	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083850		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	15401123	EXPEDITED (15-DAY)		OT	DE-ABBVIE-18K-062-2483634-00		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Failure	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Ciclosporin	S	Subcutaneous		Not Reported
	Ciclosporin	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral	Tablet	Not Reported
	Apo-Leflunomide	S	Oral	Tablet	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous Rituxan	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexat	S	Subcutaneous	20mg	Not Reported
	Methotrexat	S	Oral	20mg, Solution For Injection/Infusion	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported

Enbrel	S	Subcutaneous	50 Mg, Qw Txt		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous		Not Reported
Leflunomide	S	Unknown	Film Coated Tablet		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	C	Unknown	2 Ot, Qd		Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)		Not Reported
Xeljanz	C	Oral	2 Ot, Qd		Not Reported
Xeljanz	C	Unknown	2 Ot, Qd		Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)		Not Reported
Xeljanz	C	Oral	2 Ot, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	15688989	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1053		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alanine Aminotransferase Increased; Alopecia; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Aspartate Aminotransferase Increased; Asthenia; Basal Cell Carcinoma; Blood	Methotrexate (Trade Name Unknown)			S	Oral	Lower Doses Initially And Increased Over The Years Around 1997		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Parathyroid Hormone Decreased; Blood	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Pressure Fluctuation; Body Temperature	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Decreased; Bone Density Abnormal; C-Reactive	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Protein Increased; Chills; Contraindicated Product	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Administered; Cough; Deafness; Decreased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Appetite; Disability; Drug Eruption; Drug Ineffective;	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Drug Intolerance; Drug Tolerance; Drug Tolerance	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Decreased; Fatigue; Gastric Disorder;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Granuloma Skin; Headache;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Hypercalcaemia; Hypercholesterolaemia;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Hypersensitivity; Infection; Inflammation; Insomnia;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Limb Deformity; Loss Of Personal Independence In	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Daily Activities; Malaise; Mobility Decreased; Mood	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Swings; Musculoskeletal Pain; Musculoskeletal	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Stiffness; Nasopharyngitis; Nausea; Neck Mass;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Oropharyngeal Pain; Osteomyelitis; Pain; Pain	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
In Extremity; Panniculitis; Peripheral Swelling;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Product Use Issue; Product Use Issue;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Pyrexia; Rash; Rash Pruritic; Red Blood Cell	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Sedimentation Rate Increased; Rheumatoid	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Arthritis; Rheumatoid Lung; Rheumatoid Nodule;	Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg	Not Reported

Rosacea; Skin Necrosis; Skin Ulcer; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer; Vomiting; Weight Increased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	25	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Cyclical	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Cyclical	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	2x/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	1 Every 2 Weeks	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	2x/Week	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported

Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Indocid	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	5 Days Out Of 7, Cyclical	Not Reported
Leflunomide	S	Oral		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not		Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Indomethacin	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown	Cyclical	Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Gold (198 Au) Colloidal	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Codeine	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular	Cyclical	Not Reported
Myochrysine	S	Unknown		Not Reported
Myochrysine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported

Alendronic Acid	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Fosamax	S	Unknown		Not Reported
Acetaminophen	S	Oral		Not Reported
Benadryl	S	Oral		Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)		Not Reported
Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Oral		Not Reported
Advil	C	Unknown		Not Reported
Demerol	C	Unknown		Not Reported
Cymbalta	C	Oral	Nightly	Not Reported
Folic Acid Aventis	C	Oral		Not Reported
Folic Acid Aventis	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Cyclosporine	C	Unknown	Not Reported
	Cyclosporine	C	Unknown	Not Reported
	B Complex	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Ciprodex	C	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Leflunomide	C	Oral	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	15932044	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651975-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Hand Deformity; Headache; Hepatic Enzyme	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported

Xeljanz	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sarilumab	S	Unknown		Not Reported
Leflunomide	S	Subcutaneous		Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	15980424	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017430169		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Reaction; Injection Site Urticaria; Nausea; Rash; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	25 Milligram, Qd		Not Reported
	Atenolol			C	Oral	50 Mg, 1x/Day		Not Reported
	Simponi			C		Unk		Not Reported
	Inflectra [Infliximab]			C	Intravenous (not otherwise specified)	300 Milligram,(Q0, 2,6, Week Then Every 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	16200433	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Blood Pressure Increased; Bone Disorder; C-Reactive Protein Abnormal;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Drug Intolerance; Fall; Fatigue; Femur Fracture; Gait Disturbance; Gastric	Methotrexate (Trade Name Unknown)			S	Subcutaneous	2.5 Mg/Ml		Not Reported
Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased;	Methotrexate (Trade Name Unknown)			S	Subcutaneous	4 Every 1 Week		Not Reported
Hepatic Enzyme Increased; Infection; Joint Laxity; Joint Swelling;	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Osteopenia; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling;	Enbrel			S	Unknown			Not Reported
Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence;	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Enbrel	S	Unknown	4 Every 1 Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported

Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Subcutaneous	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Subcutaneous	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Tylenol	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported

Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Acetaminophen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown		Not Reported
Apo-Hydro	S	Unknown		Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Amaryl	S	Unknown		Not Reported
Otezla	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Tylenol With Codeine No.3	C	Unknown	As Needed	Not Reported
Synthroid	C	Unknown		Not Reported
Celebrex	C	Oral		Not Reported
Celebrex	C	Oral		Not Reported
Hydromorphone Hcl	C	Unknown		Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown		Not Reported

Methotrexate	C	Unknown			Not Reported
Methotrexate	C	Subcutaneous			Not Reported
Methotrexate	C	Subcutaneous	4 Every 1 Week		Not Reported
Methotrexate	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Methotrexate	C	Subcutaneous			Not Reported
Methotrexate	C	Unknown			Not Reported
Diphenhydramine	C	Oral			Not Reported
Glyburide	C	Unknown			Not Reported
Hydrochlorothiazide	C	Unknown			Not Reported
Lipitor	C	Unknown			Not Reported
Metformin	C	Unknown			Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)			Not Reported
Percocet	C	Unknown			Not Reported
Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	16443477	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03342		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use;	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported

Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Certolizumab Pegol	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Cimzia	S	Unknown	Unknown Solution Subcutaneous	Not Reported
	Cimzia	S	Unknown	Unknown Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Humira	S	Unknown	Unknown Solution Subcutaneous	Not Reported
	Humira	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Leflunomide	S			Not Reported
	Minocycline Hydrochloride	S	Unknown	Unknown	Not Reported
	Myochrysine	S	Subcutaneous	Unknown	Not Reported
	Myochrysine	S	Parenteral	Unknown Solution Intramuscular	Not Reported
	Myochrysine	S	Unknown	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Unknown	Not Reported
	Myochrysine	S	Unknown	Unknown Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Oral	Unknown	Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Unknown Solution Intravenous	Not Reported
	Rituxan	S	Unknown	Unknown Solution	Not Reported

			Intravenous	
Rituxan	S	Intravenous (not otherwise specified)	Unknown Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Sirukumab	S	Unknown	Unknown	Not Reported
Sirukumab	S			Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
Stelara	S	Unknown	Unknown	Not Reported
Stelara	S	Unknown	Unknown Solution Subcutaneous	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Tofacitinib Citrate	S	Oral		Not Reported
Ustekinumab	S	Unknown	Unknown	Not Reported
Ustekinumab	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous drip	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Minocycline	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Salazopyrin	S	Unknown	Unknown	Not Reported

Salazopyrin	S	Unknown	Unknown	Not Reported
Apremilast	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Minocin	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S			Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Orencia	C	Unknown	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown Powder For Solution	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	C	Unknown	Unknown	Not Reported
Orencia	C	Unknown		Not Reported
Salazopyrin	C	Unknown	Unknown	Not Reported
Rheumatrex	C	Unknown	Unknown	Not Reported
Abatacept	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Plaquenil	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	16730453	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017087863		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer

Swelling; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive	Arthrotec		S	Unknown	Unk	Pfizer
	Rituximab		S	Unknown		Pfizer
	Sulfasalazine		S	Oral	500 Milligram, Bid	Pfizer
	Leflunomide		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Rituxan		S	Unknown		Not Reported
	Asa		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Gabapentin		C		Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	16804995	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Q12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	16811263	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190905771		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Asthenia; Back Pain; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gait Disturbance; Goitre; Headache; Hospitalisation; Infection; Inflammation; Intentional Product Misuse; Joint Swelling; Loss Of Personal	Paracetamol			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			S	Unknown			Not Reported
	Paracetamol/Diphenhydramine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Independence In Daily Activities; Lower Respiratory Tract Infection; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Swelling; Therapeutic Product Effect Incomplete; Thyroid Disorder; Visual Impairment	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Doxycycline	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 823.0	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Hydroxychloroquine /00072603/	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported

Gold	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Paracetamol/Codeine Phosphate	C	Unknown	Not Reported
Oros Hydromorphone Hcl	C	Unknown	Not Reported
Tylenol W/ Codeine No. 3	C	Unknown	Not Reported
Celebrex	C	Oral	Not Reported
Celecoxib	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Oral	Not Reported
Synthroid	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Codeine	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Plaquenil /00072602/	C	Unknown	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Ketoprofen	C	Unknown	Not Reported
Losec /00661201/	C	Unknown	Not Reported
Naprosyn /00256201/	C	Unknown	Not Reported

Omeprazole	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	16822887	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2019GSK067189		26 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Infection; Alopecia; Cutaneous Lupus Erythematosus; Cutaneous Lupus Erythematosus; Dermatitis; Dermatitis Allergic; Headache; Herpes Zoster; Impaired Healing; Inappropriate Schedule Of Product Administration; Inappropriate Schedule Of Product Administration; Leukocytosis; Product Dose Omission; Pyeloplasty; Pyrexia; Pyrexia; Rash; Renal Surgery; Respiratory Tract Infection; Skin Injury; Skin Lesion; Systemic Lupus Erythematosus; Urinary Tract Infection; Weight Decreased	Belimumab			S	Intravenous (not otherwise specified)	630 Mg		Glaxosmithkline
	Belimumab			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Belimumab			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Belimumab			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Belimumab			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Belimumab			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Mycophenolate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	16842729	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3543		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alanine Aminotransferase	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Abnormal; Alanine Aminotransferase	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Increased; Arthralgia; Arthritis; Arthropathy;	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Aspartate Aminotransferase	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Increased; Basal Cell Carcinoma; Blood	Methotrexate (Trade Name Unknown)	S	Unknown	4 Times Per Week	Not Reported
Creatinine Increased; Blood Parathyroid	Methotrexate (Trade Name Unknown)	S	Unknown	4 Times Per Week	Not Reported
Hormone Decreased; Blood Pressure Systolic	Methotrexate (Trade Name Unknown)	S	Unknown	4 Times Per Week	Not Reported
Increased; C-Reactive Protein Increased;	Methotrexate (Trade Name Unknown)	S	Unknown	4 Times Per Week	Not Reported
Contraindicated Product Administered; Decreased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Appetite; Diarrhoea; Drug Eruption; Drug Ineffective;	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Drug Intolerance; Enthesopathy; Erythema;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Fatigue; Fear Of Injection; General Physical Health	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Deterioration; Granuloma Skin; Headache;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Hypercalcaemia; Hypertension;	Methotrexate (Trade Name Unknown)	S	Oral	4 Times Per Week	Not Reported
Inflammation; Insomnia; Joint Injury; Joint Swelling;	Methotrexate (Trade Name Unknown)	S	Subcutaneous	4 Times Per Week	Not Reported
Loss Of Personal Independence In Daily	Methotrexate (Trade Name Unknown)	S	Subcutaneous	4 Times Per Week	Not Reported
Activities; Musculoskeletal Stiffness; Nausea;	Methotrexate (Trade Name Unknown)	S	Subcutaneous	4 Times Per Week	Not Reported
Overdose; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Pulmonary	Methotrexate (Trade Name Unknown)	S	Unknown	12.5mg, 4 Times/Wk, .1096mg, 4 In 1 Years, .1315mg, 4 In 1 Years, 10 Mg, 12mg, 17.5mg, 4 Times/Wk, 1	Not Reported
Fibrosis; Rash; Rash Pruritic; Red Blood Cell	Etanercept	S	Subcutaneous		Not Reported
Sedimentation Rate	Etanercept	S	Unknown		Not Reported

Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Etanercept	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Ibuprofen	S	Oral	Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	2 Times/Wk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2 Times/Wk	Not Reported
	Apo Ibuprofen	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Cyclosporine	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Abatacept	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported

Stelara	S	Subcutaneous		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Ustekinumab	S	Subcutaneous		Not Reported
Ustekinumab	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Humira	S	Subcutaneous	40 (Units Unknown)	Not Reported
Humira	S	Subcutaneous	Cyclical	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Apremilast	S	Oral		Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cyclosporine	S	Oral		Not Reported
Cyclosporine	S	Unknown		Not Reported
Otezla	S	Oral		Not Reported
Otezla	S	Oral		Not Reported
Otezla	S	Unknown		Not Reported
Ciclosporin	S	Oral		Not Reported
Ciclosporin	S	Unknown		Not Reported
Ciclosporin	S	Unknown		Not Reported
Sulfamethoxazole	S	Oral		Not Reported
Motrin	S	Oral	Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Unknown		Not Reported
Motrin	S	Oral		Not Reported

Motrin	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Unknown	4 Every 1 Week	Not Reported
Codeine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous drip		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Celebrex	S	Oral		Not Reported
Cosentyx	S	Unknown		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Rituximab	S	Unknown		Not Reported
Acetaminophen	S	Unknown		Not Reported
Diphenhydramine	S	Unknown		Not Reported
Anolamine Hydrochloride	S	Unknown		Not Reported
Benadryl	S	Unknown		Not Reported

Plaquenil	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Mogadon	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported
Uloric	C	Oral	Not Reported
Uloric	C	Unknown	Not Reported
Uloric	C	Unknown	Not Reported
Uloric	C	Unknown	Not Reported
Uloric	C	Unknown	Not Reported
Uloric	C	Oral	Not Reported
Uloric	C	Oral	Not Reported
Colchicine	C	Oral	Not Reported
Colchicine	C	Oral	Not Reported
Colchicine	C	Unknown	Not Reported
Acide Folique	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Nitrazepam	C	Unknown	Not Reported
Nitrazepam	C	Oral	Not Reported
Nitrazepam	C	Oral	Not Reported
Dexilant	C	Unknown	Not Reported
Dexilant	C	Oral	Not Reported
Gravol	C	Unknown	Not Reported
Febuxostat	C	Unknown	Not Reported
Febuxostat	C	Unknown	Not Reported

	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Actonel	C	Oral		Not Reported
	Vitamin D3	C	Oral		Not Reported
	Risedronate Sodium	C	Oral		Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Unknown	Strength: 2.5 Mg	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Arava	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17115225	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019519686		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Sciatica	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Acetaminophen			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Prednisone			S		7 Mg, 1x/Day		Not Reported
	Apo-Ramipril			S		Unk, 1x/Day		Not Reported
	Folic Acid			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported
	Levothyroxine			S		Unk, 1x/Day		Not Reported

	Orencia		S		Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Acetaminophen;Codeine		C		Unk	Not Reported
	Acetaminophen;Caffeine;Dihydrocodeine Bitartrate		C		Unk	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate		C	Ophthalmic	Unk, 2x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C		400 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17287208	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00689			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use;	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown, Suspension Intra-Articular	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Gamastan	S	Intramuscular	Dosage Form Liquid Intramuscular	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17326065	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034081		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17375337	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0655		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17450142	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1058		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Wound	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Atasol [Paracetamol]			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine;Hydrochloride;Pseudo ephedrine			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported

Desoximetasone	S	Oral	Not Reported
Diclofenac	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Topicort	S	Subcutaneous	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Vitamin C	C	Unknown			Not Reported
Vitamin C	C	Unknown			Not Reported
Vitamin D	C	Unknown			Not Reported
Vitamin D	C	Unknown			Not Reported
Alaskan Salmon Oil	C	Unknown			Not Reported
Glucosamine	C	Unknown			Not Reported
Lansoprazole	C	Unknown			Not Reported
Ativan	C	Unknown	As Needed		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17721718	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004071			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Haematochezia; Hypoacusis; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Rash; Musculoskeletal Pain; Off Label Use; Osteoarthritis; Product Storage Error; Product Use Issue	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
	Dupilumab			S	Subcutaneous	600 Mg Once Via Pre-Filled Syringe		Not Reported
	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
	Dupilumab			S	Subcutaneous	300 Mg, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17731724	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004144			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hepatocellular Injury; Off Label Use;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia

Pneumothorax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17860099	EXPEDITED (15-DAY)		HO, OT	NVSC2020DO155080		33 YR	Male	DOM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Central Nervous System Lesion; Dizziness; Gait Disturbance; Gait Inability; Headache; Heart Rate Decreased; Hepatic Enzyme Increased; Hepatic Enzyme Increased; Ill-Defined Disorder; Influenza; Limb Discomfort; Lymphopenia; Multiple Sclerosis; Myalgia; Oropharyngeal Discomfort; Pyrexia; Sars-Cov-2 Test Positive; Suspected Covid-19; Tremor; Tremor	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Hidroxicloroquina			S	Unknown	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17875175	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043810		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Treatment Failure	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported
	Prednisone	C	Unknown	5 Milligram, 1 Every 1 Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17885852	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020223832			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17890783	EXPEDITED (15-DAY)		OT	CA-COLGATE PALMOLIVE COMPANY-20200601096			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Pain; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Chlorhexidine Gluconate Unspecified	S	Unknown		Colgate
	Chlorhexidine Unspecified	S	Unknown		Colgate
	Periogard Rinse Unspecified	S	Unknown		Colgate
	Oxycodone Terephthalate	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Oxycodone Hydrochloride;Paracetamol	S	Unknown		Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram, 4 Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram, 4 Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram, 1 Month, Therapy Duration: 84.0 Days	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram, 1 Month	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Abatacept	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

Simponi	S	Periarticular	Unk		Not Reported
Acetaminophen	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Sulfamethoxazole	S	Unknown			Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Chloraprep	S	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Pantoprazole	C				Not Reported
Ibuprofen	C				Not Reported
Pantoloc [Pantoprazole]	C				Not Reported
Arava	C				Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown			Not Reported
Hydroxychloroquine Sulfate	C				Not Reported
Cetrizine	C				Not Reported
Tylenol [Paracetamol]	C	Unknown			Not Reported
Paracetamol Codeine	C				Not Reported
Desogestrel And Ethinylestradiol	C				Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17926122	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-025864		25 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Augmentin			S	Oral	1 Gram, Once A Day		Not Reported
	Clexane			C	Subcutaneous	1 Dosage Form, Once A Day		Not Reported
	Dicloreum			C	Intramuscular	1 Dosage Form (Total)		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17936621	EXPEDITED (15-DAY)		OT	CA-ACCORD-185837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate			S	Intra-arterial	1every 1 Days		Accord
	Alendronate Sodium/Alendronic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Abatacept			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	1 Every 1 Days	Not Reported
	Sulfasalazine		S	Unknown	1 Every 12 Hours	Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Methotrexate		S	Oral		Accord
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17976882	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-051855		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Orencia			S	Endocervical	200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	10 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	20 Nanogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2 Gram, Q6mo		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Risedronate Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17981752	EXPEDITED (15-DAY)		OT	CA-ACCORD-187301		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Minocycline			S				Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported
	Arava			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Xeljanz			S		Frequency: 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17982473	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202006006849			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Potassium Decreased; Blood Sodium Increased; Off Label Use; Pyrexia; Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Q12h (Every 12 Hours)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Omeprazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Furosimide			C		Unk		Not Reported
	Insulin;Insulin Human			C		Unk		Not Reported
	Cephalosporin Nos			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17988504	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		57 YR	Female	CAN

BMS-2020-053947

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Gold			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18010234	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-053858		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Gram, Q6mo		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, 2 Every 1 Day		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, 2 Every 1 Day		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18051522	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006656		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Unevaluable Event	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Apotex
	Minocycline			S	Unknown	50 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	100 Milligram		Apotex

Arava	S	Oral	20 Milligram, Q.Wk.	Not Reported
Arava	S			Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Q.Wk.	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	400 Milligram	Not Reported
Humira	S	Unknown	40 Milligram, Q.O.Wk.	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Q.Wk.	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	5 Nanogram, Bid	Not Reported
Orencia	S	Unknown	Unk, Q.M.T.	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	C	Unknown	Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
Amoxil /00249601/	C	Unknown	Unk	Not Reported
Bcg	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bcg	C	Intravesical	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Amoxicillin	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
Hydroxychloroquine	C	Unknown	100 Milligram	Not Reported

	Hydroxychloroquine	C	Subcutaneous	40 Milligram	Not Reported
	Risedronate	C	Oral	35 Milligram, Q.Wk.	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18068411	EXPEDITED (15-DAY)		OT	CA-ACCORD-191927		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Adalimumab			S	Unknown	1 Every 2 Weeks		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Orencia			S	Unknown	1 Every 1 Weeks		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Abatacept			S	Unknown	1 Every 1 Weeks		Not Reported
	Tylenol			C	Unknown	4 Every 1 Days		Not Reported
	Gabapentin			C	Oral	3 Every 1 Days		Not Reported
	Xeljanz			C	Oral	1 Every 1 Days		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18069092	EXPEDITED (15-DAY)		OT	CA-ACCORD-191906		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S				Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Frequency: 1 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S				Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18101400	EXPEDITED (15-DAY)		DS, OT	CA-ACCORD-193656		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 1 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	1 Every 1 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	1 Every 1 Weeks	Not Reported
	Erelzi		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18168168	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016076		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Leflunomide			S	Unknown	20 Milligram		Apotex
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18176987	EXPEDITED (15-DAY)		HO	CA-APOTEX-2020AP015983			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Milligram		Apotex
	Methotrexate			C	Unknown	20 Milligram, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18177098	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP015970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased;	Hydroxychloroquine			S	Unknown	Unk		Apotex

Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Leflunomide		S	Unknown	10 Milligram	Apotex
	Leflunomide		S	Unknown	20 Milligram	Apotex
	Cosentyx		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk, Therapy Duration - 151, Unit Unspecified	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18180997	EXPEDITED (15-DAY)		OT	CA-ACCORD-196507		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Accord
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Medroxyprogesterone			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Elavil			S	Unknown			Not Reported
	Depo Provera			C	Intramuscular			Not Reported

	Kineret	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18181492	EXPEDITED (15-DAY)		OT	CA-ACCORD-196514		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Not Specified		Accord
	Actemra			S	Unknown	Not Specified		Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Enbrel			S	Unknown	Not Specified		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous drip	Not Specified		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18181721	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP015974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Hydroxychloroquine			S	Unknown	200 Milligram		Apotex
	Leflunomide			S	Unknown	20 Milligram (Therapy Duration: 423 (Unit Unspecified))		Apotex
	Methotrexate			S	Unknown	25 Milligram (Therapy Duration: 761 (Unit Unspecified))		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported

	Prednisone		C	Unknown	50 Milligram	Not Reported
	Xeljanz		C	Oral	5 Milligram, Q.12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18191924	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-066665		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, 1 Every 21 Weeks		Bristol Myers Squibb
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18209069	EXPEDITED (15-DAY)		DS	CA-COLGATE PALMOLIVE COMPANY-20200801603			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Confusional State; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Periogard Rinse Unspecified	S	Buccal		Colgate
	Chlorhexidine Unspecified	S	Topical	Unk	Colgate
	Chlorhexidine Unspecified	S	Unknown	Unk	Colgate
	Chlorhexidine Gluconate Unspecified	S	Unknown		Colgate
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, 1 Day	Not Reported
	Methotrexate	S	Oral	20 Milligram, 1 Week	Not Reported
	Prednisone	S	Oral	7.5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Oxycodone Terephthalate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Fosamax	S	Oral		Not Reported
	Cortisone	S	Topical	25 Milligram	Not Reported
	Cimzia	S	Subcutaneous		Not Reported

Oxycodone;Paracetamol	S	Unknown		Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Cetirizine	S			Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram	Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	3011.2 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	728 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	2912 Milligram	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Xeljanz	S	Unknown	10 Milligram	Not Reported
Xeljanz	S			Not Reported
Pseudoephedrine	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S			Not Reported
Atasol [Paracetamol]	C			Not Reported

	Ibuprofen	C	Not Reported
	Tylenol With Codeine	C	Not Reported
	Pantoprazole	C	Not Reported
	Cetirizine	C	Not Reported
	Tylenol [Paracetamol]	C	Not Reported
	Desogestrel;Ethinylestradiol	C	Not Reported
	Pantoloc [Pantoprazole]	C	Not Reported
	Salazopyrina	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18216943	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016796		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Milligram, Q.Wk.		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate Sodium			C	Unknown	25 Milligram, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18233464	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2020027880			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Levofloxacin 500 Mg			S	Unknown	500 Milligram, Qd		Macleods
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18237577	EXPEDITED (15-DAY)		OT	CA-ACCORD-199551		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Oral			Accord
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous	Powder For Suspension		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18248869	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA025705			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous			Not Reported

Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Apo-Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25.0 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Folic Acid	S			Not Reported
	Folic Acid	S	Unknown	1.0 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral	25.0 Milligram	Not Reported
	Methotrexate	S			Not Reported

Methotrexate	S	Oral	20.0 Milligram (1 Every 1 Day)	Not Reported
Methotrexate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Oral	500.0 Milligram	Not Reported
Phthalylsulfathiazole	S	Oral	1000.0 Milligram (2 Every 1 Day)	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400.0 Milligram (1 Every 1 Day)	Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1000.0 Milligram (2 Every 1 Day)	Not Reported
Sulfasalazine	S			Not Reported
Sulfasalazine	S	Oral	500.0 Milligram	Not Reported
Sulfasalazine	S			Not Reported
Tofacitinib	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown	5.0 Milligram (2 Every 1 Day)	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous		Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18248897	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025714			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Anaphylactic Reaction; Arthralgia; Blood Glucose Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg 1 Every 1 Week		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Prednisone	S	Urethral	25 Mg 1 Every 1 Day		Not Reported
Prednisone	S				Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown	1 Df 1 Every 1 Day		Not Reported
Pregabalin	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sodium Aurothiomalate	S	Parenteral			Not Reported
Sulfasalazine	S	Unknown	1.5 Mg 2 Every 1 Day		Not Reported
Levothyroxine	C	Unknown			Not Reported
Morphine	C	Unknown			Not Reported
Piroxicam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18265083	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-047497		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ischaemic Stroke; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S				Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Gentamicin			S				Not Reported
	Ampicillin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

	Kaletra	S	Unknown	Unk		Not Reported
	Kaletra	S				Not Reported
	Vancomycin	S	Unknown	Unk		Not Reported
	Vancomycin	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18273556	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1827382		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjacent Segment Degeneration	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18286206	EXPEDITED (15-DAY)		DS, LT, OT	NVSC2020CA249017			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain;	Cetirizine Hydrochloride			S	Unknown	10 Mg		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Novartis
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cortisone Acetate			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported

Pemphigus; Pericarditis; Product Use In Unapproved Indication; Product Use Issue; Rash	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18288336	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017831		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Chlorhexidine			S	Unknown	Unk		Apotex

Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Pain; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Methotrexate	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported
	Oxycodone/Acetaminophen	S	Unknown	Unk	Not Reported
	Trimethoprim/Sulfamethoxazole	S	Unknown	Unk	Apotex
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram, Q.M.T.	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram (1 Dose Every 4 Weeks)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram, Q.M.T.	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Unk (1 Dose Every 4 Weeks)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	725 Unk (1 Edose Very 4 Weeks)	Not Reported
	Chloraprep	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Periogard	S	Buccal	Unk	Not Reported
	Simponi	S	Periarticular	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Chlorhexidine	S	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Cetirizine	C	Unknown	Unk	Not Reported

	Desogestrel & Ethinyl Estradiol	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Paracetamol Codeine	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Tylenol With Codeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18289139	NON-EXPEDITED			US-PFIZER INC-2020361769		76 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Levothyroxine Sodium			S		Unk		Pfizer
	Flexeril			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Alprazolam			C	Oral	1 Mg, As Needed (Take 1tablet Every Day By Oral Route As Needed)		Not Reported
	Amitriptyline			C	Oral	Unk, Daily (0.5 Tablets Every Day By Oral Route)		Not Reported
	Bystolic			C	Oral	5 Mg, Daily (Take 1 Tablet Every Day By Oral Route)		Not Reported
	Vitamin D3			C	Oral	1250 Ug, 1x/Day (Cholecalciferol (Vitamin D3) 1,250 Mcg (50,000 Unit) Capsule, Po, Qd)		Not Reported
	Hydrocodone Bitartrate And			C	Oral	1 Df, 4x/Day		Not Reported

	Acetaminophen			(Hydrocodone 10 Mg-Acetaminophen 325 Mg Tablet)	
	Ibuprofen	C	Oral	200 Mg, As Needed (Take 1 Tablet Every Day By Oral Route As Needed)	Not Reported
	Lyrica	C	Oral	50 Mg, Daily (Take 1 Capsule Every Day By Oral Route)	Not Reported
	Prednisone	C	Oral	2.5 Mg, 2x/Day	Not Reported
	Pregabalin	C		75 Mg	Not Reported
	Tylenol	C		Unk, As Needed (Prn)	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18298356	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA027075			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin;	Rituximab (Unknown)			S	Unknown	1000 Mg, 2x/Day		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg, Qd		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg, Q12h		Not Reported
	Enbrel			S	Unknown	50.0 Milligram 1 Every 1 Weeks		Not Reported
	Etanercept			S	Unknown	50 Mg, Weekly		Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Unk		Not Reported

Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Overdose; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Not Reported

Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day (Formulation: Solution For Intravesical Use)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day (Formulation: Solution For Intravesical Use)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day (Formulation: Solution For Intravesical Use)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day (Formulation: Solution For Intravesical Use)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine	S	Unknown		Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Milligram, Qwk	Not Reported
Actemra	S	Unknown	360 Mg	Not Reported
Actemra	S	Unknown	360 Mg	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, 1/Week	Not Reported
Orencia	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Orencia	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported

Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Gold	S	Unknown		Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C	Unknown	10 Mg, Unk	Not Reported
Prednisone	C	Unknown	10 Mg	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Cyclosporin	C	Unknown	150 Mg, 1x/Day	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, 2x/Day	Not Reported
Xeljanz	C	Oral	11 Milligram, Qd	Not Reported
Prednisolone	C	Unknown		Not Reported
Leflunomide	C	Oral	20 Milligram	Not Reported
Leflunomide	C	Unknown	20 Milligram	Not Reported
Leflunomide	C		Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Arava	C	Unknown	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316335	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1831167			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate	S	Unknown		Barr
	Acetaminophen	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Actavis
	Leflunomide	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not		Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous drip		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Dosage Forms Daily;	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Topicort	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Salazopyrina	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316708	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026748			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)					
	Mobicox			C	Unknown	15 Mg, Qd (1 Every 1 Day)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316725	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026801			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Off Label Use; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Cyclophosphamide			S	Unknown	150 Milligram, 1 Every 24 Hours		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, 1 Every 24 Hours		Not Reported
	Mycophenolate Mofetil			S	Oral	1 Every 24 Hours		Not Reported
	Mycophenolate Mofetil			S	Unknown	720 Milligram, 2 Every 1 Days		Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316730	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026809			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1.0 Gram		Not Reported
	Celebrex			S	Unknown	200.0 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram, 1 Every 1 Days		Not Reported

Methotrexate	S	Subcutaneous	Unk, 1 Every 1 Days		Not Reported
Naproxen	S	Unknown	500.0 Milligram, 2 Every 1 Days		Not Reported
Orencia	S	Subcutaneous	150.0 Milligram, 1 Every 1 Months		Not Reported
Simponi	S	Subcutaneous	50.0 Milligram, 1 Every 1 Months		Not Reported
Sulfasalazine	S	Unknown	500.0 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316748	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202009008813			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corrective Lens User; Dermatitis Contact; Eye Disorder; Eye Pain; Immunodeficiency; Pruritus; Stress; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316793	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202009008797			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Heart Valve Incompetence; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	600 Mg, Qd		Concordia
	Lansoprazole			C				Not Reported
	Abatacept			C				Not Reported
	Adalimumab			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316996	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06476		53 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk (Loading Dose : 2 X400)		Lupin
	Hydroxychloroquine			S	Unknown	Unk (Maintenance Treatments : 2 X 200)		Lupin
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18316999	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-06367		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Sepsis; Hypotension; Off Label Use; Septic Shock	Hydroxychloroquine			S	Unknown	200 Milligram Bid		Lupin
	Tocilizumab			C	Unknown	400 Milligram		Not Reported
	Epoprostenol			C		Unk (She Was Treated For 4 Days With Inhaled Epoprostenol.)		Not Reported
	Levofloxacin			C	Unknown	500 Milligram		Not Reported
	Levofloxacin			C				Not Reported
	Dexamethasone			C	Unknown	2 Milligram		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	1 Gram		Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317005	EXPEDITED (15-DAY)		OT	SI-LUPIN PHARMACEUTICALS INC.-2020-06477		48 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	On The First Day		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	From Second Day Onwards		Lupin

	Lopinavir/Ritonavir	C	Intravenous (not otherwise specified)	1 Dosage Form	Not Reported
	Piperacillin/Tazobactam	C	Unknown	1 Dosage Form	Not Reported
	Dalteparin	C	Unknown	7500 International Unit	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Midazolam	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Unknown	40 Milligram, Qd	Not Reported
	Fentanyl	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Noradrenaline [Norepinephrine]	C	Unknown	Unk	Not Reported
	Iviglob-Ex	C	Unknown	1 G/Kg Of Adjusted Body Weight Divided Into Two Daily Doses	Not Reported
	Nadroparin	C	Unknown	5600 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317007	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026906			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317014	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026844			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317053	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026562			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Off Label Use; Toe Amputation	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate			S	Oral	25 Milligram, 1 Every 1 Weeks		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Prednisone	C	Oral	5 Milligram, 2 Every 1 Days	Not Reported
	Restasis	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317058	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026572			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1 Every 1 Days		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317064	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026621			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Duloxetine Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

	Folic Acid	C	Unknown	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317068	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026626			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	162 Mg		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317077	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026649			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported

Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Nystatin	S	Unknown	Not Reported
	Nystatin	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Indometacin	C		Not Reported
	Prednisone	C		Not Reported
	Tramadol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317078	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026633			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Actemra			S	Unknown	200 Mg, 1 Every 1 Month		Not Reported
	Arava			S	Oral	20 Mg, 1 Every 24 Hours		Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	1 Mg, 1 Every 24 Hours		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317136	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027003			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Meningitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	1.0 Dosage Form		Not Reported

	Enbrel	S	Subcutaneous	50.0 Milligram	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317166	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027244			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	20.0 Mg		Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Diclofenac Sodium & Misoprostol			S	Unknown	50.0 Mg, 1 Every 12 Hrs		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, 1 Every 12 Hrs		Not Reported
	Leflunomide			S	Unknown	20.0 Mg		Not Reported
	Leflunomide			S	Unknown	20.0 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Methotrexate	S	Subcutaneous	7.5 Mg		Not Reported
Methotrexate	S	Subcutaneous	20.0 Mg		Not Reported
Methotrexate	S	Unknown	7.5 Mg		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Arthrotec	C	Unknown	50.0 Mg, 1 Every 12 Hrs		Not Reported
Ergocalciferol	C	Unknown			Not Reported
Gold	C	Unknown			Not Reported
Imuran [Azathioprine]	C	Unknown			Not Reported
Vitamin D [Colecalciferol]	C	Unknown			Not Reported
Vitamin D3	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317171	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA027059			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Decreased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported
	Acetaminophen			S	Oral	65.0 Milligram		Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520.0 Milligram, 1 Every 4 Weeks		Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5.0 Milligram		Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300.0 Milligram, 1 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks		Not Reported

Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Methotrexate	S	Subcutaneous	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Prednisone	S	Unknown	7.5 Milligram	Not Reported
	Prednisone	S	Unknown		Not Reported
	Alendronate Sodium;Vitamin D3	C	Unknown		Not Reported
	Diphenhydramine	C	Unknown		Not Reported
	Humira	C	Unknown		Not Reported
	Hydrocortisone	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported
	Methylprednisolone	C	Unknown		Not Reported
	Orencia	C	Unknown		Not Reported
	Remicade	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317185	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027226			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	2000 Mg		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1/Week		Not Reported
	Humira			S	Subcutaneous	40 G		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other	Unk		Not Reported
	Methotrexate			S	Other			Not Reported
	Orencia			S	Subcutaneous	750 Mg, 1/Week		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317230	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027006			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317262	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026758			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20.0 Milligram, 1 Every 24 Hours		Not Reported

Cimzia	S	Subcutaneous			Not Reported
Enbrel	S	Unknown	50.0 Milligram, 1 Every 1 Weeks		Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Days		Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Meloxicam	C	Unknown			Not Reported
Methotrexate	C	Unknown	Unk, 1 Every 1 Weeks		Not Reported
Synthroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317278	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026919			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Weight Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317280	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026922			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituximab (Unknown)		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400.0 Milligram	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317286	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026935			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular	25.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Methotrexate			S	Oral	25.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, Qd (1 Every 1 Days)		Not Reported
	Enbrel			S	Unknown	50.0 Mg, 1/Week (1 Every 1 Weeks)		Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317287	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027017			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amoxicillin;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Bacillus Calmetteguerin Bcg			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317312	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026840			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gait Inability; Movement Disorder; Nausea; Off Label Use; Pain; Weight Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317350	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026897			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	25.0 Milligram 2 Every 1 Weeks	Not Reported
	Etanercept	S	Subcutaneous	25.0 Milligram 2 Every 1 Weeks	Not Reported
	Gold	S	Intramuscular		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317377	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027138			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral	25 Mg, 1 Every 1 Week		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C	Unknown			Not Reported
	Remicade			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317380	EXPEDITED (15-DAY)		DS	CA-ACCORD-202790		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S		1 Every 1 Days		Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Arava			S	Oral	1 Every 1 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Indocid			S				Not Reported
	Indometacin			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S		1 Every 1 Days		Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Oral	2 Every 1 Days		Not Reported
	Leflunomide			S		1 Every 1 Days		Not Reported
	Cymbalta			C	Oral	1 Every 1 Days		Not Reported
	Folic Acid			C	Oral			Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317392	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027195			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317399	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027201			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317429	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027238			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317449	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026987			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500.0 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500.0 Milligram		Not Reported
	Desoximetasone			C	Unknown	10.0 Milligram, 1 Every 24 Hours		Not Reported
	Diclofenac			C	Unknown	100.0 Milligram, 1 Every 1 Days		Not Reported
	Voltaren [Diclofenac]			C	Unknown	100.0 Milligram, 1 Every 24 Hours		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317569	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026876			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317571	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027239			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100.0 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317583	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA027242			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituximab (Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317609	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027309			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown	100.0 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown	100.0 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram		Not Reported

	Methotrexate	S	Subcutaneous	25.0 Milligram	Not Reported
	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown	50.0 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	5.0 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown		Not Reported
	Amoxil [Amoxicillin]	C	Unknown		Not Reported
	Bcg	C	Intravenous (not otherwise specified)		Not Reported
	Bcg	C	Unknown	Unk	Not Reported
	Gold	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317622	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027312			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317639	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026925			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	400 Milligram		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317643	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027287			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317647	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026911			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Rituximab (Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1 Every 1 Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18317843	NON-EXPEDITED			US-ALLERGAN-2029812US		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Dislocation; Knee Arthroplasty; Rash; Skin Haemorrhage; Suspected Covid-19; Therapy Interrupted	Alphagan			S				Allergan
	Lexapro			S		20 Mg, Qd		Allergan
	Xeljanz Xr			S		11 Mg, Qd		Not Reported
	Aleve			S		500 Mg, Prn		Not Reported
	Xanax			S		0.5 Mg, Bid		Not Reported
	Centrum			S		Unk, Qd		Not Reported
	Clonazepam			S		1 Mg, Qd		Not Reported
	Doxycycline Monohydrate			S		100 Mg, Qd		Not Reported
	Hydroxychloroquine			S		200 Mg, Tid		Not Reported
	Levetiracetam			S		500 Mg, One And Half		Not Reported

			Tablet, Three Times A Day	
	Pregabalin	S	150 Mg, Bid	Not Reported
	Rivastigmine	S	1 Df, Qd	Not Reported
	Spironolactone	S	1 Df, Qd	Not Reported
	Methocarbamol	S	500 Mg, Bid	Not Reported
	Tizanidine	S	4 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318253	EXPEDITED (15-DAY)		OT	CA-ACCORD-202903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral	1 Every 24 Hours		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	1 Every 24 Hours		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral	1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318255	EXPEDITED (15-DAY)		OT	CA-ACCORD-202904			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis	Methotrexate		S	Oral		Accord
	Hydroxychloroquine		S	Oral	2 Every 1 Days	Not Reported
	Indometacin		S	Oral	4 Every 1 Days	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Arava		S	Unknown		Not Reported
	Actemra		S	Intravenous (not otherwise specified)	1 Every 1 Months	Not Reported
	Indometacin		C			Not Reported
	Hydroxychloroquine		S	Oral	2 Every 1 Days	Not Reported
	Indometacin		S	Oral	3 Every 1 Days	Not Reported
	Indometacin		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318256	EXPEDITED (15-DAY)		OT	CA-ACCORD-202913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Metaraminol			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318257	EXPEDITED (15-DAY)		OT	CA-ACCORD-202906			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Eye Disorder; Hip Surgery; Hypertension; Pneumonia; Post Procedural Infection; Restless Legs Syndrome	Methotrexate			S	Unknown			Accord
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rofact [Rifampicin]			S	Unknown			Not Reported
	Chlormezanone			C				Not Reported
	Colchicine			C				Not Reported
	Dexilant			C				Not Reported
	Diclofenac			C				Not Reported
	Hydromorphone			C				Not Reported
	Prednisone			C				Not Reported
	Quetiapine/Quetiapine Fumarate			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318307	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06359		14 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Leflunomide			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318317	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1836		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ill-Defined Disorder;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Synovitis	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Minocycline	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Rheumatrex [Methotrexate Sodium]	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Depo-Medrol	C	Unknown		Not Reported
	Aleve	C	Unknown		Not Reported
	Robax	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Tylenol Extra Strength	C	Unknown	Prn	Not Reported

Nexium [Esomeprazole Magnesium]	C	Unknown			Not Reported
Ventolin	C	Unknown	Prn		Not Reported
Vitamin B 12	C	Unknown			Not Reported
Vit D	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318321	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027423			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	11.2 Milligram, 1 Every 1 Day		Not Reported
	Arava			S	Unknown	20 Milligram, 2 Every 2 Days		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	20 Milligram, 1 Every 1 Week		Not Reported
	Plaquenil			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram		Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318341	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-06364		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318365	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026479			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318418	EXPEDITED (15-DAY)		OT	CA-ACCORD-202805		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug	Methotrexate			S	Subcutaneous			Accord
	Actemra			S				Not Reported

Ineffective; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Baclofen		S		Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S		Not Reported
	Humira		S	Subcutaneous	Not Reported
	Naproxen		S	Oral	Not Reported
	Orencia		S		Not Reported
	Plaquenil		S		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfadiazine/Sulfadiazine Silver/Sulfadiazine Sodium		S		Not Reported
	Xeljanz		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318423	EXPEDITED (15-DAY)		HO	CA-ACCORD-202911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Accord
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Methotrexate		S	Unknown	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318535	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026406			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Mg 1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318926	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06478		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Vancomycin			S	Unknown	Unk		Lupin
	Natalizumab			C	Unknown	Unk Administered Monthly		Not Reported
	Piperacillin/Tazobactam			C	Intracardiac	Unk		Not Reported

	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318931	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027545			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Rituximab (Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown			Not Reported
	Breo Ellipta			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dexilant			S	Oral	60 Milligram, 1 Every 1 Days		Not Reported
	Estrogel			S	Topical	1 Every 1 Days		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ventolin Hfa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318966	EXPEDITED (15-DAY)		OT	CA-ACCORD-202563		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolic Acid		S	Unknown	Accord
	Sulfasalazine		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Lyrica		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Gold/Gold Keratinate/Gold Monosulfide/Gold Trisulfide		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Piroxicam		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18318975	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2020M1081848		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Ceftriaxone			S		2000 Milligram, Qd		Not Reported
	Piperacillin/Tazobactam			S		Unk		Mylan
	Enoxaparin			S		6000 International Unit (6000 Iu (Axa)		Mylan
	Enoxaparin			S				Mylan
	Methylprednisolone			S		1 Milligram/Kilogram, Qd		Mylan
	Spiramycin			S		4.5 Mega-International Unit, Qd (1.5 Miu, 3x/Day)		Not Reported
	Voriconazole			S	Intravenous (not	8 Milligram/Kilogram, Qd		Mylan

			otherwise specified)	(4 Mg/Kg, 2x/Day)	
	Voriconazole	S	Intravenous (not otherwise specified)	12 Milligram/Kilogram, Qd (6 Mg/Kg, 2x/Day)	Mylan
	Hydroxychloroquine	S		400 Milligram, Qd (200 Mg, 2x/Day)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319046	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026515			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 1 Months		Not Reported
	Alendronate			S	Oral	70 Milligram, 1 Every 1 Weeks		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	25 Milligram, 2 Every 1 Weeks		Not Reported
	Etanercept			S	Unknown	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 11 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	12 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	15 Milligram, 1 Every 1 Weeks		Not Reported

	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Weeks	Not Reported
	Myochrysine	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319266	EXPEDITED (15-DAY)		OT	CA-ACCORD-202559		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Also Received 20.0 Mg 1 Every 1 Days		Accord
	Alendronate Sodium/Alendronic Acid			S	Unknown			Accord
	Phthalylsulfathiazole			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Pseudoephedrine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Golimumab			S	Unknown			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Cortisone	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319344	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3580926-00		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Simponi	C	Subcutaneous		Not Reported
	Naproxen	C			Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319358	EXPEDITED (15-DAY)		OT	NVSC2020PT257926		83 YR	Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	250 Mg, Qd (D1 500mg)		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd (D1: 400mg 12/12h)		Not Reported
	Lopinavir + Ritonavir			S	Oral	4 Df, Qd (2cp 12/12h, Comprimido Revestido Por Película)		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Remifentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ketamine			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk(Solução Injetável)		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported
	Piperacilin/Tazobactam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Human Serum Albumin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Quetiapine			C	Oral	Unk		Not Reported

	Methylprednisolone	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	Unk	Not Reported
	Aas	C	Oral	Unk (Comprimido)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319539	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077170		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen [Naproxen Sodium]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319540	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077165		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Erelzi [Etanercept]			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Unknown	420 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319682	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026399			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319692	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026489			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, 1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	200 Mg, 2 Every 1 Days		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Days		Not Reported
	Methotrexate			S	Vaginal	25 Mg, 4 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Weeks		Not Reported
	Orencia			S	Unknown	1 Every 1 Days		Not Reported

Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 4 Weeks	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, 1 Every 1 Months	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg	Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Tocilizumab	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Anakinra	C	Unknown	100 Mg	Not Reported
Anakinra	C	Unknown	100 Mg	Not Reported
Ativan	C	Unknown	1 G, 1 Every 1 Days	Not Reported
Ativan	C	Unknown	1 Mg, 1 Every 1 Days	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Darifenacin	C	Unknown		Not Reported
Darifenacin	C	Oral	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intra-articular	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Dexmethasone	C	Unknown		Not Reported
Dilaudid	C	Unknown	4 Mg, 4 Every 1 Days	Not Reported
Dilaudid	C			Not Reported
Dilaudid	C			Not Reported
Dilaudid	C	Unknown	4 Mg, 1 Every 1 Days	Not Reported
Dilaudid	C	Unknown	4 Mg	Not Reported
Dilaudid	C			Not Reported
Diphenhydramine	C	Unknown		Not Reported

Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Dyclone	C	Unknown		Not Reported
Furosemide	C	Unknown	40 Mg, 3 Every 1 Days	Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Mg	Not Reported
Lasix [Furosemide]	C	Unknown	40 Mg, 3 Every 1 Days	Not Reported
Leflunomide	C	Unknown		Not Reported
Loperamide	C	Unknown	2 Mg, 2 Every 1 Day	Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	2 Every 1 Days	Not Reported
Omnaris	C	Unknown		Not Reported
Orphenadrine	C	Unknown	1 Df, 2 Every 1 Days	Not Reported
Orphenadrine Citrate	C	Unknown	1 Df, 2 Every 1 Days	Not Reported
Orphenadrine Citrate	C	Unknown	2 Every 1 Days	Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoloc [Pantoprazole]	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported
Restasis	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Mg	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Mg	Not Reported
Vagifem	C	Vaginal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319709	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026512			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400.0 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Milligram		Not Reported
	Leflunomide			S	Unknown	20.0 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 4 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	20.0 Milligram, 4 Every 1 Weeks		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, 2 Every 1 Days		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5.0 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319734	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026565			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported

Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319735	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026544			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	25.0 Milligram, 1 Every 1 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319943	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026578			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319946	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026747			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Atorvastatin Calcium	C	Unknown		Not Reported
	Irbesartan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18320605	EXPEDITED (15-DAY)		OT	TR-SLATE RUN PHARMACEUTICALS-20TR000284			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown			Not Reported
	Favipiravir			S	Unknown			Not Reported
	Low Molecular Weight Heparin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18320705	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2020371947		83 YR	Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day(D1 500mg)		Pfizer
	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	D1: 400mg 12/12h		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Df, 2x/Day (2 Tablets 12/12h)		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Remifentanil			C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported

Ketamine	C		Unk		Not Reported
Esomeprazole	C				Not Reported
Ipratropium Bromide	C	Respiratory (inhalation)			Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)			Not Reported
Enoxaparin Sodium	C				Not Reported
Piperacillin / Tazobactam	C	Intravenous (not otherwise specified)	Unk		Not Reported
Furosemide	C				Not Reported
Human Serum Albumin	C	Intravenous (not otherwise specified)	Unk		Not Reported
Quetiapine	C	Oral			Not Reported
Methylprednisolone	C				Not Reported
Lorazepam	C				Not Reported
Aas	C	Oral			Not Reported
Albumin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18321214	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1082070		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydrocortisone			S	Unknown			Mylan
	Hydroxychloroquine			S	Oral	400 Milligram, Total		Mylan
	Kaletra			S	Oral	Unk Unk, Bid		Mylan
	Oseltamivir			S	Oral	75 Milligram, Qd		Mylan
	Cellcept /01275102/			C	Unknown	Unk		Mylan
	Cellcept /01275102/			C	Unknown	500 Milligram, Bid		Mylan
	Cyclosporin			S	Unknown	75 Milligram, Bid		Mylan
	Cefepime			C	Intravenous (not otherwise specified)	500 Milligram, Bid		Mylan
	Vancomycin			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18321218	EXPEDITED (15-DAY)		OT	CH-TEVA-2020-CH-1832883		62 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Fibrinogen Increased; Hepatocellular Injury; Off Label Use	Hydroxychloroquine			S	Unknown			Teva
	Atazanavir			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Remdesivir			C				Not Reported
	Unfractionated Heparin			C		Standard-Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18321280	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832196			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Oral Discomfort; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Tofacitinib		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18321297	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020370338		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S	Oral	Unk (Every 1 Days)		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Brenzys			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18321547	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2018GSK149085		38 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circumstance Or Information Capable Of Leading To Medication Error; Inappropriate Schedule Of Product Administration; Product Dose Omission; Tuberculosis	Benlysta			S		Unk		Glaxosmithkline
	Azathioprine			S		Unk		Glaxosmithkline
	Ranitidine			S		Unk		Glaxosmithkline
	Alodipine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18321620	EXPEDITED (15-DAY)		DE	US-AMNEAL PHARMACEUTICALS-2020-AMRX-02957			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome	Hydroxychloroquine Sulfate			S	Unknown	600 Milligram, 2x/Day On Day 1		Amneal
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2x/Day For		Amneal

	Prednisone		C	Unknown	5 Days 5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18322248	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1832330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Methotrexate			S	Unknown			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18323435	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200932802		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Cephalexin /00145501/	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18324358	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-078473		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qwk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18324588	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077294		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Infection; Inflammation; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Weeks	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Qmo (1 Every 1 Months)	Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk 1 Every 1 Week	Not Reported
	Fentanyl	S	Unknown		Not Reported
	Gabapentin	S	Oral	100 Milligram 2 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram 1 Every 1 Days	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram 1 Every 3 Week	Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Gram 1 Every 1 Days	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram 1 Every 1 Month Solution Itravenous	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	400 International Unit 1 Every 1 Days	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram 2 Every 1 Days	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram 1 Every 1 Days	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	1 Every 1 Days	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	2.5 Milligram	Not Reported
	Lomotil [Loperamide Hydrochloride]	C	Unknown	2.5 Milligram	Not Reported

Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C	Unknown	1200 Milligram 2 Every 1 Days		Not Reported
Pantoprazole Magnesium	C	Unknown	1 Every 1 Days		Not Reported
Perphenazine	C	Oral	1 Every 1 Days		Not Reported
Prednisone	C	Unknown	1 Every 1 Days		Not Reported
Risedronate Sodium	C	Unknown	36 Milligram 1 Every 1 Week		Not Reported
Trazodone Hydrochloride	C	Unknown	50 Milligram 1 Every 1 Days		Not Reported
Tylenol	C	Oral	500 Milligram		Not Reported
Tylenol	C	Oral	1000 Milligram, Qd		Not Reported
Xeljanz	C	Unknown	5 Milligram 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18325043	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2020-049638		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebral Venous Thrombosis; Confusional State; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18325062	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA028689			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Infliximab			S		Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported

Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Product Use In Unapproved Indication; Synovitis	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Morphine Sulfate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	S	Oral	2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Day	Not Reported
	Etanercept	S		Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk (Unit=Prefilled Syringe)	Not Reported
	Cimzia	S	Unknown	Unk (Unit=Prefilled Syringe)	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S			Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

Otezla	S	Unknown	Unk	Not Reported
Otezla	S	Oral	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sirukumab	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Dilaudid	C		Unk	Not Reported
Dilaudid	C		Unk	Not Reported
Dilaudid	C		Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Bupropion Hydrochloride	C		Unk	Not Reported
Hydromorphone Hydrochloride	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18325097	EXPEDITED (15-DAY)		OT	ES-CELLTRION INC.-2020ES028139			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Suspected Covid-19	Rituximab (Unknown)		S	1 G/15 Days/6 Months Or 375 M2/Week X 4	Not Reported
	Prednisolone		S	5 Mg/Day	Not Reported
	Hydroxychloroquine		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18325180	EXPEDITED (15-DAY)		LT, OT	ES-AUROBINDO-AUR-APL-2020-049546		91 DAY	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Seizure	Levetiracetam			S	Unknown	28 Milligram/Kilogram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	6.5 Milligram/Kilogram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	12764755	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

	Sulfasalazine	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	12769017	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-024540		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Qmo		Not Reported

	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk Unk, Prn	Not Reported
	Folic Acid	C	Unknown	Unk Unk, Prn	Not Reported
	Naproxen	C	Unknown	Unk Unk, Prn	Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk Unk, Prn	Not Reported
	Ketorolac	C	Unknown	Unk, Prn	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Methotrexate	C	Subcutaneous	20 Mg, Qwk	Not Reported
	Leflunomide	C	Unknown	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	12769487	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Orencia			S		Unk		Bristol Myers Squibb
	Tylenol			S	Unknown	As Needed		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk(Loe)		Not Reported
	Enbrel			S	Unknown	40 Milligram 4 Every One Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported

Heart Rate Increased; Hepatic Enzyme Increased; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Use Issue; Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Therapeutic Product Effect Incomplete; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	200 Unk (6 Months)	Not Reported
	Sulfasalazine	S	Unknown	Unk, 5 Months	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	800 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Unknown	325 Milligram	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Apo Hydro	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	200 Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 24 Hours	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Doxycycline	S	Unknown	100 Milligram, Bid	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown	20 Nanogram	Not Reported
Apo-Prednisone	S	Unknown	20 Milligram, Qd	Not Reported
Diphenhydramine Hydrochloride;Paracetamol	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	25 Dosage Form	Not Reported
Methotrexate	S	Unknown	Unk, Qwk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tylenol W/Codeine	C	Unknown		Not Reported
Celebrex	C	Oral	200 Mg, Bid	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

Celecoxib	C	Unknown			Not Reported
Codeine	C	Unknown			Not Reported
Leflunomide	C	Unknown	20 Milligram, 2 Every 1 Day		Not Reported
Diphenhydramine	C	Oral	50 Milligram		Not Reported
Glyburide (Micronized)	C	Unknown	Unk		Not Reported
Hydrochlorothiazide	C	Unknown	Unk		Not Reported
Lipitor [Atorvastatin]	C	Unknown			Not Reported
Metormin	C	Unknown			Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
Amaryl [Glimepiride]	S	Unknown			Not Reported
Otezla	S	Unknown			Not Reported
Stelara	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	12769492	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076352			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Insomnia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Anakinra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	Unk, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
	Naprosyn [Naproxen]	S	Unknown	500 Milligram, 2 Times/Wk	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, Qd	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Vioxx	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Oral	500.0 Milligram, Bid	Not Reported
	Naproxen	S	Oral	500 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S			Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Leflunomide	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	12770684	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076867		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Subcutaneous	1 Dosage Form, Qwk		Bristol Myers Squibb
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Phosphate]				
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Fentanyl	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S			Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, Qmo	Not Reported
	Actemra	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram, Qh	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Q3wk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Celecoxib	S	Oral		Not Reported
	Apo Celecoxib	S	Oral		Not Reported
	Xeljanz	S	Oral	5 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Fentanyl Matrix	S	Unknown		Not Reported
	Nortriptyline Hydrochloride;Perphenazine	S	Oral	10 Milligram, Qd, Cyclical	Not Reported
	Gabapentin	S	Oral	100 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone	C	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Aclasta	C	Unknown	488 Milligram, Qmo	Not Reported
	Actonel	C	Unknown	36 Mg, Qwk	Not Reported
	Ascorbic Acid	C	Unknown		Not Reported

Biotin	C	Unknown		Not Reported
Calcium	C	Unknown	Unk Unk, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	C	Unknown		Not Reported
Diphenoxylate Hcl	C	Unknown	2.5 Milligram, Qd	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	Unk, Qd	Not Reported
Epa Dha 720	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
Esomeprazole	C		40 Milligram, Bid	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, 2 Every 1 Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
Ferrous Fumarate	C	Unknown		Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Fish Oil	C	Unknown	1200 Milligram, Bid	Not Reported
Folic Acid	C	Unknown		Not Reported
Genteal [Hypromellose]	C	Ophthalmic	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
Loperamide	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	40 Mg, Bid	Not Reported
Vitamin B3	C	Unknown		Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Oxycodone And Acetaminophen	C	Unknown		Not Reported

Oxycodone Terephthalate	C	Unknown		Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram, Qd	Not Reported
Perfenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram, Q2h	Not Reported
Pyridoxine	C	Unknown		Not Reported
Retinol Palmitate	C	Unknown		Not Reported
Riboflavin	C	Unknown		Not Reported
Thiamine Hcl	C	Unknown		Not Reported
Thiamine Mononitrate	C	Unknown		Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Cyclical	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qh	Not Reported
Sodium	C	Unknown		Not Reported
Sodium Ascorbate	C	Unknown		Not Reported
Tylenol	C	Oral	1000 Mg, Qd	Not Reported
Vitamin D3	C	Unknown		Not Reported
Vitamin A [Retinol]	C	Unknown		Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown		Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	400 Dosage Form, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
Multivitamin [Ascorbic Acid;Biotin;Calcium Pantothenate;Cyanocobalamin	C	Unknown		Not Reported
Omega 3 2100	C	Unknown	1200 Milligram, Bid	Not Reported
Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]	C	Unknown	1 Dosage Form, As Required	Not Reported
Pyridoxine Hydrochloride	C	Unknown		Not Reported

	Tecta	C	Unknown	40 Milligram, Qd	Not Reported
	Vitamin B1 [Thiamine]	C	Unknown		Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown		Not Reported
	Acetaminophen	C	Oral	1000 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Nortriptyline Hydrochloride	S			Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown		Not Reported
	Zoledronic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	12842578	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1958		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Inappropriate Schedule Of Product Administration; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash;	Methotrexate (Trade Name Unknown)			S	Oral	Cyclic		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral	Cyclic		Not Reported
	Methotrexate (Trade Name			S	Oral	(Cyclical)		Not Reported

Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Unknown)				
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Apo Folic Acid	S	Unknown	Twice In A Week	Not Reported
	Apo Folic Acid	S	Unknown	Twice A Week	Not Reported
	Naprosyn E	S	Oral		Not Reported
	Naprosyn E	S	Oral		Not Reported

Naprosyn E	S	Oral	Not Reported
Naprosyn E	S	Oral	Not Reported
Naprosyn E	S	Oral	Not Reported
Naprosyn E	S	Oral	Not Reported
Naprosyn E	S	Oral	Not Reported
Naprosyn E	S	Oral	Not Reported
Naprosyn E	S	Unknown	Not Reported
Palafer Cf	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Abatacept	S	Unknown	Not Reported

Ascorbic Acid	S	Unknown		Not Reported
Ferrous Fumarate	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown	2/Week	Not Reported
Folic Acid	S	Unknown	2/Week	Not Reported
Folic Acid	S	Unknown	2/Week	Not Reported
Folic Acid	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Ferrous Fumarate-Folic Acid	S	Unknown		Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Atenolol	S	Oral		Not Reported
Atenolol	S	Oral		Not Reported

Remicade	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Palafer	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Pantoprazole Teva	S	Unknown	Not Reported
Pantoprazole Teva	S	Unknown	Not Reported
Pantoprazole Teva	S	Unknown	Not Reported
Pantoprazole Teva	S	Unknown	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Not Reported
Cyto-Matrix Vitamin C	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S	Oral	Not Reported
Celecoxib	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported

	Celebrex	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Celecoxib	C	Oral	Not Reported
	Celecoxib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	12928888	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Joint Swelling; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qh		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qcycle		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported

Decreased; Nausea; Nodule; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qh	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Qcycle	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Actonel	S	Oral	35 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qh	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Cyclical	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Form, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Risedronate Sodium	S	Oral	35 Milligram, Qwk		Not Reported
Risedronate Sodium	S	Unknown	16.35 Milligram, Q2wk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Xeljanz	S	Oral	10 Milligram, Qd		Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Risedronic Acid	S	Unknown	35 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Risedronate	C	Unknown	35 Milligram, Qwk		Not Reported
Risedronate	C	Unknown	Unk		Not Reported
Methotrexate	C	Subcutaneous	Unk		Not Reported
Prednisone	C	Unknown	10 Milligram, Two Every One Day		Not Reported
Prednisone	C	Unknown	5 Milligram,One Every One Day		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	13058435	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015741		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased;	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Sulfasalazine	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran /00001501/	S	Unknown	Unk		Not Reported
	Methyl Salicylate	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	13246191	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006577		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Pain; Pain In Extremity	Apo-Azathioprine			S	Unknown	50 Mg, Tid		Not Reported
	Apo-Azathioprine			S	Unknown	150 Milligram, Tid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Milliequivalent, Qd		Apotex
	Celebrex			S	Oral	400 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	13393764	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-068945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	13851389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported

Ineffective; Drug Intolerance; General Symptom; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Mobicox	C	Unknown	15 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	14400613	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2017193304		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint	Enbrel			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Subcutaneous	Unk		Amgen
	Pantoloc [Pantoprazole]			S	Unknown	40 Milligram, Qd		Not Reported
	Pantoloc [Pantoprazole]			S	Unknown	40 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Cyclical, Every 2 Weeks		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Q2wk		Not Reported

Swelling; Multiple Fractures; Musculoskeletal Pain; Off Label Use; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	Unk Unk, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Cyclical, Once Every 2 Weeks	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	Unk Unk, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Atenolol	S	Oral	25 Milligram, Qd	Not Reported
	Atenolol	S	Oral	20 Milligram, Qd	Not Reported

Celecoxib	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Milligram, Qd	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
Co Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
Co Atenolol	S	Unknown	20 Milligram, Qd	Not Reported
Naprosyn E	S	Oral	100 Milligram, Qd	Not Reported
Naprosyn E	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn E	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn E	S	Oral	1000 Milligram, Qd	Not Reported
Naprosyn E	S	Unknown	Unk	Not Reported
Naprosyne	S	Oral	100 Milligram, Qd	Not Reported
Naprosyne	S	Oral	500 Milligram, Qd	Not Reported
Naprosyne	S	Oral	500 Milligram, Bid	Not Reported
Naprosyne	S	Oral	1000 Milligram, Qd	Not Reported
Palafer Cf	S	Unknown	Unk Unk, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Ferrous Fumarate + Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported

Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Ascorbic Acid	S	Unknown	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk Unk, Qd	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
Folic Acid	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Bid	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, Bid	Not Reported

	Naproxen Sodium	S	Unknown	1000 Milligram, Qd	Not Reported
	Naproxen Sodium	S	Unknown	500 Milligram, Bid	Not Reported
	Naproxen Sodium	S	Unknown	100 Milligram, Bid	Not Reported
	Naproxen Sodium	S	Unknown	1000 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Palafer	S	Unknown	Unk	Not Reported
	Pantoprazole Sodium	S	Unknown	40 Milligram, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Celebrex	C	Oral	200 Milligram, Qd	Not Reported
	Celebrex	C	Oral	Unk	Not Reported
	Celecoxib	C		Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15059046	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015918		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Salazopyrin	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Actemra	C	Unknown	Unk		Not Reported
Align	C	Unknown	Unk		Not Reported
Loperamide	C	Oral	2 Mg, Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Pantoprazole	C				Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15067535	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015876		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Salazopyrin	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Loperamide	C	Oral	2 Mg, Unk		Not Reported
Pantoprazole	C	Unknown	Unk, Tid		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Actemra	C	Unknown	Unk		Not Reported
Align	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15076377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Off Label Use; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15088344	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016068			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Apotex
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported
	Acetaminophen			C	Unknown	500 Mg, Unk		Not Reported
	Aurothiomalate De Sodium			C	Unknown	Unk		Not Reported
	Hydrocortisone Valerate			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Lyderm /00280401/			C	Unknown	Unk		Not Reported
	Myocrisin			C	Unknown	1 Every 2 Weeks		Not Reported
	Naproxen			C	Unknown	250 Mg, Qd		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Sodium Aurothiomalate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15233081	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015249702		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly (Qwk)	Pfizer
	Methotrexate Sodium	S	Unknown	20 Mg, Q2wk	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Qd	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Milligram	Pfizer
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Pfizer
	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qd	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Qwk	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic, Every 2 Weeks (Q2wk)	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk (Solution Subcutaneous)	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	12.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg	Not Reported

Kineret	S	Subcutaneous	100 Mg, 1x/Day	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
Anakinra	S	Unknown	100 Milligram, Qd	Not Reported
Anakinra	S	Subcutaneous	100 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclic, Every 4 Weeks (Q4wk)	Not Reported
Orencia	S	Unknown	500 Mg, Cyclical	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4mo	Not Reported
Orencia	S	Unknown	500 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, 1x/Day	Not Reported
Apo-Hydroxyquine	S	Unknown	20 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	Unk, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15332862	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram, Q.Wk.		Apotex

Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Apotex
Hydroxychloroquine	S	Unknown	300 Milligram	Apotex
Actemra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk, One Every Six Weeks	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk, Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	25 Milligram, Q.O.Wk.	Not Reported
Enbrel	S	Unknown	25 Mg, Unk, Cyclical	Not Reported
Enbrel	S	Unknown	25 Milligram, Q.Wk.	Not Reported
Enbrel	S	Subcutaneous	25 Milligram	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Wellbutrin	C	Oral	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Bupropion	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15333912	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019346			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S	Unknown			Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk, Qd		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15657201	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20181128756		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Off Label Use; Onychomadesis; Onychomycosis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Infliximab	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15683328	EXPEDITED (15-DAY)		HO, LT, OT	CA-CELLTRION INC.-2018CA024265			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency;	Infliximab Pfizer (Unknown)			S	Intravenous (not	3 Mg/Kg, Weekly (1 Every		Not Reported

Antibody Test Positive; Arthralgia; Arthritis; Arthritis; Arthropathy;	Infliximab Pfizer (Unknown)	S	otherwise specified)	1 Week)	
Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk	Not Reported
	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)	Not Reported
	Infliximab Pfizer (Unknown)	S	Unknown	Unk	Not Reported
	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))	Not Reported
	Infliximab Pfizer (Unknown)	S	Unknown	3 Mg, Weekly	Not Reported
	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab Pfizer (Unknown)	S		1 Dosage Form, Qwk	Not Reported
	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Every Two Week	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 1x/Day	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 4times/Wk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	1.5 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	4 Dosage Form, Qwk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Bid	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Methotrexate Sodium	S		15 Mg/M2, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported

Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk, Weekly	Not Reported
	Methotrexate Sodium	S		15 Mg, 2x/Week	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Not Reported
	Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
	Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Triamcinolone	S		Unk	Not Reported
	Triamcinolone	S		Unk	Not Reported
	Infliximab	S	Unknown	3 Mg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Cyclic	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported

Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
Triamcinolone Acetonide	S		Unk	Not Reported
Xeljanz Xr	S	Unknown	11 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1 Every 24 Hour(S))	Not Reported
Hydroxychloroquine	S	Oral	5 Mg/Kg, Daily	Not Reported
Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported
Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S		Unk	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S		Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S))	Not Reported

Anakinra	S	Subcutaneous	Unk, Qd	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	50 Milligram	Not Reported
Anakinra	S	Unknown	50 Milligram, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S))	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S)	Not Reported
Orencia	S	Unknown	250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported

Actemra	S	Intravenous (not otherwise specified)	280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1x/Day Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Qwk	Not Reported
Actemra	S	Subcutaneous	161 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1x/Day	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1	Not Reported

			Day(S))	
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo-Prednisone	S	Oral	Unk	Not Reported
Apo-Prednisone	S	Oral	Unk	Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Gammagard	S		Unk	Not Reported
Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	1 Dosage Form, Qd	Not Reported
Gamastan	S	Intramuscular	70 G, Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15719053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245381		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache;	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Subcutaneous	50 Mg		Unknown
	Enbrel			S	Unknown	50 Mg		Unknown
	Methotrexate Sodium			S	Subcutaneous	17.5 Milligram, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	0.8 Mg/Kg, Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Kineret	S	Subcutaneous	100 Mg, Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	300 Mg, Daily ((200mg:1 And A Half Pill), Qd)	Not Reported
	Plaquenil	S	Oral	300 Mg, 1x/Day, Qd	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Mg	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic: On Day 0 And Day 15	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Gold	S	Other	Unk	Not Reported
Anakinra	S	Subcutaneous	100 Milligram, Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	20 Mg, Every Hour	Not Reported
Apo-Hydroxyquine	S		20 Mg, Daily (Every Hour)	Not Reported
Actonel	S	Oral	35 Milligram, Qwk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Mg, 1x/Day, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Mg, Cyclic, Qh	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Mg	Not Reported
Apo-Leflunomide	S		Unk, 1x/Day	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S			Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qh	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk, Qwk	Not Reported
Risedronate	S	Oral	35 Milligram, Qwk	Not Reported
Risedronate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	300 Mg, 1x/Day, Qd	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day, Qd	Not Reported

	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk Unk, Qd	Not Reported
	Hydroxychloroquine	S		300 Mg, Unk	Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
	Risedronate	C	Unknown	35 Milligram, Qwk	Not Reported
	Prednisone	C		10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	15741776	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181218371		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Chest Pain; Disease Susceptibility; Drug Ineffective; Epicondylitis; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Upper Limb Fracture	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Procytox			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported

	Neoral	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Imuran /00001501/	S	Unknown	Not Reported
	Bupropion	C		Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	16156314	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034439		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S				Barr
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Simponi	S				Not Reported
Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported
Sulfasalazine	S				Not Reported
Xeljanz	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Naprosyn	S	Unknown	100 Milligram Daily;		Not Reported
Celebrex	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	16483146	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017349309		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1.0 Dosage Form, Qd		Not Reported
	Hydroxychloroquine			S	Oral	300 Mg, 1x/Day		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, 1 Every 1 Hour(S)	Not Reported
Leflunomide	S	Unknown	1.0 Dosage Form	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Mg, 1x/Day	Not Reported
Actonel	S	Unknown	35.0 Mg, Weekly	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Risedronate	S	Unknown	Unk	Not Reported
Risedronate	S		35 Mg, Weekly	Not Reported
Methotrexate	C		Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	16613478	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20190721988		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Stelara			S	Subcutaneous			Not Reported

Parathyroid Hormone Decreased; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Fatigue; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Incorrect Route Of Product Administration; Inflammation; Influenza Like Illness; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect	Motrin	S	Oral	Not Reported
	Motrin	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Treatment Failure; Ulcer	Otezla	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Infliximab	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported

Humira	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Ciclosporin	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Ibuprofen	S	Oral	Not Reported
Ibuprofen	S	Oral	Not Reported
Ibuprofen	S	Oral	Not Reported
Alendronate Sodium	S	Unknown	Not Reported

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Cosentyx	S	Oral	Not Reported
Diclofenac	S	Oral	Not Reported
Leucovorin Calcium	S	Oral	Not Reported
Meloxicam	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Pantoprazole	S	Oral	Not Reported
Pantoprazole Magnesium	S	Unknown	Not Reported
Synthroid	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Celebrex	S	Oral	Not Reported
Colchicine	C	Oral	Not Reported
Febuxostat	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported
Mogadon	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Uloric	C	Oral	Not Reported
Uloric	C	Unknown	Not Reported
Uloric	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Nitrazepam	C	Oral	Not Reported

	Nitrazepam	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Dexilant	C	Oral	Not Reported
	Dexilant	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Diltiazem Hydrochloride	C	Oral	Not Reported
	Fluticasone Propionate	C		Not Reported
	Pantoprazole Sodium Sesquihydrate	C	Unknown	Not Reported
	Mometasone Furoate	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported
	Alendronate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17146157	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20191207479		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Motrin			S	Oral			Not Reported
	Motrin			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Stelara			S	Unknown			Not Reported

Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; General Physical Health Deterioration; Headache; Hepatic Enzyme Increased; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Nausea; Off Label Use; Pain; Psoriatic Arthropathy; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Otezla	S	Oral	Not Reported
	Otezla	S	Oral	Not Reported
	Otezla	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apremilast	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Sulfamethoxazole	S	Oral	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Etanercept	S		Not Reported
	Etanercept	S		Not Reported
	Tofacitinib	S	Unknown	Not Reported

Methotrexate	S	Unknown	1 Every 1 Weeks	Not Reported
Actemra	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Colchicine	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Mogadon	C	Unknown		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Oral		Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Oxyneo	C	Unknown	Tablet (Extended-Release)	Not Reported
Oxyneo	C	Unknown		Not Reported
Uloric	C	Oral		Not Reported
Uloric	C	Unknown		Not Reported
Uloric	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Golimumab	C			Not Reported
Golimumab	C			Not Reported
Golimumab	C			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17315416	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018196569		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	Dosage Form: Unspecified		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline
	Desoximetasone			S	Oral	Dosage Form: Unspecified		Glaxosmithkline
	Folic Acid			S		1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Mg		Glaxosmithkline
	Folic Acid			S		500 Mg, Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Milligram		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Actemra			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Intracorpus Route		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk Milligram		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Dosage Form: Unspecified		Not Reported
	Phthalylsulfathiazole			S	Unknown	Dosage Form: Unspecified		Not Reported
	Plaquenil			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous	Not Reported
	Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Dosage Form: Unspecified	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1 G Two Every 1 Day	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17526171	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07695		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown	Unknown		Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17566370	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200320198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Condition Aggravated; Constipation; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance; Fatigue; Gastric Bypass; Gastric Disorder; Hypersensitivity; Ill-Defined Disorder; Nausea; Off Label Use; Pain; Pain In Extremity; Product Dose Omission; Rheumatoid Arthritis; Swelling; Synovitis; Treatment Failure; Tremor; Weight Decreased	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Indocid /00003805/			S	Unknown			Not Reported
	Iodine /00080001/			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Indometacin			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Acyclovir /00587301/			S	Oral			Not Reported

	Hydromorphone Hydrochloride	S	Oral	Not Reported
	Ultram /00599202/	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Methadone	C		Not Reported
	Aspirin /00002701/	C		Not Reported
	Benadryl /00000402/	C		Not Reported
	Cymbalta	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17577763	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329927		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Back Injury; Back Pain; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Proteinuria; Rheumatoid Arthritis; Swelling; Treatment Failure;	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Vasculitis	Azathioprine	C	Oral	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)	Not Reported
	Docusate Sodium	C	Unknown	Not Reported
	Doxycycline	C	Oral	Not Reported
	Elavil /00002202/	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Tobramycin	C	Intraocular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17605652	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332789		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration 2.0 Years		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Vaginal			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Lyrica	S	Vaginal	Not Reported
Lyrica	S	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17623403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342132		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Interstitial Lung Disease; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Red	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17688732	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200411522		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Blood Pressure Increased; Contraindicated Product	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gout; Hepatic Enzyme Increased; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Metabolic Surgery; Middle Insomnia; Migraine; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Off Label Use; Osteomyelitis; Pain In Extremity; Peripheral Swelling; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Sensitivity To Weather Change; Swelling; Synovitis; Therapeutic Product Effect Decreased; Weight Increased	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Chloroquine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

	Allopurinol	C	Unknown		Not Reported
	Clomipramine	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoloc /01263201/	C	Unknown		Not Reported
	Zyloprim	C	Unknown		Not Reported
	Fentanyl	C	Unknown	Transdermal Patch	Not Reported
	Fentanyl	C			Not Reported
	Fentanyl Citrate	C	Unknown	Liquid Epidura	Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17688810	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200200876		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17715446	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033914			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17724350	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010222		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Joint Swelling; Pulmonary Mass	Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	400 Milligram	Apotex
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	800 Mg, 1 Every 4 Weeks	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg, Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Cetirizine	C	Unknown	Unk	Not Reported
	Cranberry [Vaccinium Spp.]	C	Unknown	Unk	Not Reported
	Olopatadine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Quinapril Hydrochloride	C	Unknown	Unk	Not Reported
	Sandoz Rabeprazole	C	Unknown	Unk	Not Reported
	Singulair	C	Unknown	Unk	Not Reported
	Rabeprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17758059	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437409		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituximab Gp2013	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17791142	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-181309			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Torsade De Pointes	Hydroxychloroquine			S		Twice On Day 1, Then 400 Mg Daily On Days 2 Through 5		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17849690	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP007784		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Apo-Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, Qd		Not Reported
	Apo-Azathioprine			S	Unknown	20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Cellcept /01275102/			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	500 Mg, Q.O.Wk.		Not Reported
	Rituxan			S	Intravenous (not	1000 Mg, Q.O.Wk.		Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram	Not Reported
	Rituximab	S			Not Reported
	Diphenhydramine Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
	Acetaminophen	C	Oral	1000 Milligram, Prn	Not Reported
	Acetaminophen	C	Unknown	100 Mg, Qd	Not Reported
	Methylprednisolone Sodium Succinate	C	Intravenous (not otherwise specified)	Unk, Bid	Not Reported
	Methylprednisolone Sodium Succinate	C	Unknown	Unk, Bid	Not Reported
	Methylprednisolone Sodium Succinate	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17873623	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017450		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; No Adverse Event; Off Label Use; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (Duration: 731 Unit Unknown)		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Endocervical	Unk		Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Venlafaxine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Q.M.T (One Every One Month)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Q.M.T (One Every One Month)		Not Reported

Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Q.W.K (One Every One Month)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	0.8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	40 Mg, Once Every Two Weeks	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Intravenous (not otherwise specified)	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	20 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Oral	40 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	(Duration: 578 Unit Unknown)	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram, Q.Wk. (Duration: 731 Unit Unknown)	Not Reported

Orencia	S	Intravenous (not otherwise specified)	0.75 Mg, Q.M.T (One Every One Month)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Mg/Kg, Q.M.T (One Every One Month)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram		Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Q.M.T.		Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram/Kilogram, Q.M.T.		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Plaquenil /00072602/	S	Endocervical	Unk, Unknown		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Humira	C	Unknown	Unk, Unknown		Not Reported
Prednisone	C	Unknown	Unk, Unknown		Not Reported
Azathioprine	S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17875845	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200609641		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Ciclosporin	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Cimzia	C	Subcutaneous	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17925871	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200623650		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Ineffective; Drug Intolerance; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Risedronate Sodium			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo Risedronate			S				Not Reported

Anakinra	S	Oral	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Arava	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17934256	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-047515		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17970202	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200635871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Condition	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hypersensitivity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Decreased; Visual Impairment	Remicade	S		Not Reported
	Remicade	S		Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S		Not Reported
	Simponi	S		Not Reported
	Tylenol	S	Unknown	Not Reported
	Tylenol	S		Not Reported
	Acetaminophen	S	Endocervical	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not	Not Reported

		otherwise specified)	
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Subcutaneous	Not Reported
Rituximab	S	Unknown	Not Reported
Apo-Acetaminophen	S	Unknown	Not Reported
Entyvio	S	Intravenous (not otherwise specified)	Not Reported
Entyvio	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Panadeine Co	C		Not Reported
Meloxicam	C	Unknown	Not Reported

	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Acetaminophen W/Codeine	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Leflunomide	C	Oral	Not Reported
	Phosphoric Acid	C		Not Reported
	Acetaminophen W/Codeine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	17981280	EXPEDITED (15-DAY)		OT	NVSC2020FR185485		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Neutropenia; Thrombocytopenia	Paroxetine Hydrochloride			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Novartis
	Furosemide			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	500 Mg, Unknown		Not Reported
	Amiodarone Hydrochloride			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sarilumab			S	Subcutaneous	400 Mg, 1x		Not Reported

Enoxaparin Sodium	S	Unknown	Unk		Not Reported
Levothyroxine	C	Unknown	Unk		Not Reported
Lansoprazole	C	Unknown	Unk		Not Reported
Gabapentin	C	Unknown	Unk		Not Reported
Seresta	C	Unknown	Unk		Not Reported
Racecadotril	C	Unknown	Unk		Not Reported
Tamsulosin	C	Unknown	Unk		Not Reported
Amlor	C	Unknown	Unk		Not Reported
Clopidogrel	C	Unknown	Unk		Not Reported
Eplerenone	C	Unknown	Unk		Not Reported
Alprazolam	C	Unknown	Unk		Not Reported
Kcl	C	Unknown	Unk		Not Reported
Hydroxyzine	C	Unknown	Unk		Not Reported
Melatonine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18016158	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055536		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18017458	EXPEDITED (15-DAY)		DE, HO, OT	MX-ADVANZ PHARMA-202006006997			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Lymphocyte Count Decreased; Off Label Use; Respiratory Failure	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18066181	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200725746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Condition Aggravated; Deformity; Demyelinating Polyneuropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Steatosis; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thrombocytopenia; Treatment Failure	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prevnar 13			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

	Taltz	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Inh	C	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Cosentyx	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18093078	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP014441			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Atorvastatin			S	Oral	40 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Milligram		Apotex
	Methotrexate			S	Oral	25 Milligram, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	500 Milligram		Not Reported

Folic Acid	C	Oral	5 Milligram, Q.Wk.		Not Reported
Vitamin D3	C	Oral	Unk		Not Reported
Asa Ec	C	Oral	81 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18125056	EXPEDITED (15-DAY)		DS, LT, OT	CA-JNJFOC-20200745661		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Fibromyalgia; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Liver Injury; Maternal Exposure During	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Pregnancy;	Enbrel	S	Subcutaneous	Not Reported
Musculoskeletal Stiffness; Nausea; Oedema; Off	Enbrel	S	Subcutaneous	Not Reported
Label Use; Pain;	Enbrel	S	Subcutaneous	Not Reported
Pemphigus; Pericarditis;	Cimzia	S	Subcutaneous	Not Reported
Prescribed Overdose;	Cimzia	S	Subcutaneous	Not Reported
Product Use Issue;	Actemra	S	Subcutaneous	Not Reported
Psoriatic Arthropathy;	Actemra	S	Intravenous (not otherwise specified)	Not Reported
Rash; Rheumatoid	Actemra	S	Intravenous (not otherwise specified)	Not Reported
Arthritis; Rheumatoid	Humira	S	Subcutaneous	Not Reported
Factor Positive; Swelling;	Humira	S	Subcutaneous	Not Reported
Synovitis; Systemic Lupus	Humira	S	Subcutaneous	Not Reported
Erythematosus;	Humira	S	Subcutaneous	Not Reported
Therapeutic Response	Humira	S	Subcutaneous	Not Reported
Decreased; Treatment	Humira	S	Unknown	Not Reported
Failure; Vomiting;	Humira	S	Unknown	Not Reported
Wheezing; Wound	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Oral	Not Reported
Folic Acid	S	Subcutaneous	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Adalimumab	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Cortisone	S	Oral	Not Reported
Cortisone	S	Unknown	Not Reported

Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Topicort /00028604/	S	Cutaneous	Not Reported

Topicort /00028604/	S	Unknown	Not Reported
Topicort /00028604/	S	Subcutaneous	Not Reported
Topicort /00028604/	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Reactine /00884302/	S	Unknown	Not Reported
Reactine /00884302/	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Topicort /00370301/	S	Topical	Not Reported
Topicort /00370301/	S	Subcutaneous	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Topical	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

Sulfasalazine	S	Unknown	Not Reported
Topicort /00028604/	S	Unknown	Not Reported
Actemra	S	Topical	Not Reported
Actemra	S	Unknown	Not Reported
Folic Acid	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Cosentyx	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Golimumab	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported

Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S		Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Folic Acid	S	Oral	Not Reported
Humira	S		Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Leflunomide	S		Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Desoximetasone	S		Not Reported
Orencia	S		Not Reported
Topicort /00028604/	S	Cutaneous	Not Reported
Celebrex	S	Oral	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S		Not Reported
Leflunomide	C	Unknown	Not Reported
Salazopyrine	C		Not Reported
Atasol /00020001/	C		Not Reported
Tofacitinib	C		Not Reported
Zyrtec /00884302/	C		Not Reported
Xeljanz	C	Unknown	Not Reported
Ibuprofen	C		Not Reported
Prinivil	C		Not Reported
Cholecalciferol	C		Not Reported
Calcium	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Quetiapine	C	Unknown	Not Reported

	Ramipril	C	Unknown	Not Reported
	Calcium Gluconate	C	Unknown	Not Reported
	Magnesium	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Risedronate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18171795	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016103		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18172662	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP015998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Leflunomide			S	Unknown	20 Milligram		Apotex
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

	Infliximab			S	Intravenous (not otherwise specified)	520 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18182413	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP015991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18194044	EXPEDITED (15-DAY)		HO, OT	NVSC2020US232575			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Intraventricular Haemorrhage Neonatal; Low Birth Weight Baby;	Azithromycin			S	Transplacental	Unk, Maternal Dose Unknown		Novartis
	Hydroxychloroquine			S	Transplacental	Unk, Maternal Dose Unk		Not Reported

Neonatal Respiratory Distress Syndrome; Patent Ductus Arteriosus; Premature Baby	Betamethasone	S	Transplacental	Unk, Maternal Dose Unk	Not Reported
	Nitric Oxide	S	Transplacental	Unk, Maternal Dose Unk	Not Reported
	Tocilizumab	S	Transplacental	Unk, Maternal Dose Unk	Not Reported
	Magnesium	S	Transplacental	Unk, Maternal Dose Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18200697	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2020-05159			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Sepsis Neonatal	Azithromycin			S	Transplacental	500 Milligram		Lupin
	Ceftriaxone			S	Transplacental	1 Gram		Lupin
	Methylprednisolone			S	Transplacental	40 Milligram		Lupin
	Hydroxychloroquine Sulfate			S	Transplacental	200 Milligram, Unk		Lupin
	Oseltamivir			S	Transplacental	75 Milligram, Unk		Lupin
	Favipiravir			S	Transplacental	200 Milligram, Unk		Not Reported
	Piperacillin			S	Transplacental	4.5 Milligram		Not Reported
	Enoxaparin			S	Transplacental	0.6 Milligram		Not Reported
	Insulin			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18214564	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181216733		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Off Label Use	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Amaryl			S	Oral			Not Reported

Amaryl	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Otezla	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Vioxx	S	Unknown	Not Reported
Vioxx	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18218843	EXPEDITED (15-DAY)		OT	NVSC2020IT235376		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash	Clarithromycin			S	Unknown	Unk		Novartis
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	500 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18222604	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016869			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram		Apotex
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18227974	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Diclofenac	S	Unknown	Unk	Apotex
	Methotrexate	S	Unknown	20 Milligram, Q.Wk.	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk, Qd	Not Reported
	Tramadol	C	Oral	Unk, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18238950	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1824710		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Covid-19 Pneumonia; Off Label Use	Prednisone			S	Unknown	40 Milligram Daily; 40 Mg/Day Prednisone For 30 Days Followed By Dose Tapering Of 5 Mg/Day Per Week.		Actavis
	Vitamin D3			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18248918	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025712			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia;	Rituximab (Unknown)			S	Intravenous (not	Unk		Not Reported

Chronic Sinusitis; Diarrhoea; Diverticulum; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure			otherwise specified)			
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	20.0 Milligram		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400.0 Milligram, Every 1 Days		Not Reported
	Sulfasalazine	S	Oral	1.0 Gram, 2 Every 1 Days		Not Reported
	Xeljanz	S	Oral	5.0 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18248925	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA025724			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Rash; Syncope; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg (Therapy Duration: 365)		Not Reported
	Arava			S	Oral	10 Mg, 1 Every 1 Day (Therapy Duration: 365)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic (Therapy Duration: 366)		Not Reported
	Humira			S	Subcutaneous	50 Mg, 1 Every 1 Week		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Day		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25 Mg, 1/Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram (1 Every 1 Month) (Therapy Duration:		Not Reported

				638)	
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram (2 Every 1 Day)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram 1 Every 1 Month (Therapy Duration: 396)	Not Reported
	Prednisone	C	Unknown	5 Mg, 1 Every 1 Day	Not Reported
	Prednisone	C	Unknown	50 Mg, 1 Every 1 Day	Not Reported
	Prevacid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18281166	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-AUROBINDO-AUR-APL-2020-048163		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use; Treatment Failure	Ceftriaxone			S	Unknown	2000 Milligram, Once A Day		Aurobindo
	Enoxaparine			S	Unknown	6000 International Unit (Axa)		Not Reported
	Voriconazole Powder For Solution For Infusion			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram, Two Times A Day		Aurobindo
	Voriconazole Powder For Solution For Infusion			S	Intravenous (not otherwise specified)	6 Milligram/Kilogram, Two Times A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Methylprednisolone			S	Unknown	1 Milligram/Kilogram, Once A Day		Not Reported
	Piperacillin;Tazobactam			S	Unknown	Unk		Not Reported
	Piperacillin;Tazobactam			S				Not Reported
	Spiramycin			S	Unknown	1.5 Mega-International Unit, 3 Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18282717	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1079656		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Azithromycin			S	Unknown			Mylan
	Levetiracetam			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan
	Clonazepam			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	250 Milligram, Qd Pulse Dose		Mylan
	Acetaminophen			C	Unknown			Mylan
	Bisoprolol			C	Unknown			Mylan
	Enoxaparin			C	Unknown			Mylan
	Omeprazole			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18284452	EXPEDITED (15-DAY)		DS, OT	CA-ALVOGEN-2020-ALVOGEN-114351		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity;	Atenolol			S	Oral			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Ascorbic Acid			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Ferrous Fumarate			S	Unknown			Not Reported
	Ferrous Fumarate/Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown	400.0ug Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported

Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	40.0mg Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Palafer Cf	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Celebrex	C	Oral		Not Reported
	Celecoxib	C			Not Reported
	Celecoxib	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Celebrex	C	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Pantoprazole	S	Unknown		Not Reported

	Pantoprazole	S	Unknown		Not Reported
	Naprosyn	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5.0mg Unknown	Not Reported
	Folic Acid	S	Unknown	5.0mg Unknown	Not Reported
	Folic Acid	S	Unknown	5.0mg Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0mg Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40.0mg Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0mg Unknown	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Methotrexate	S	Oral	25.0mg Unknown	Not Reported
	Methotrexate	S	Oral	20.0mg Unknown	Not Reported
	Methotrexate Sodium	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18288657	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020182463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline

Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hand Deformity; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18296532	EXPEDITED (15-DAY)		OT	NVSC2020CA254062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Cetirizine Hydrochloride			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Mg		Not Reported
	Cetirizine Hydrochloride			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Alendronate Sodium Trihydrate	S	Oral	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	40 Mg	Not Reported
Hydroxychloroquine	S	Oral	40 Mg, Qd	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	40 Mg	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S	Subcutaneous	1 G, Bid	Not Reported
Sulfasalazine	S	Oral	100 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	Unk, Bid	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Diclofenac Potassium	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	50 Mg	Not Reported
Diclofenac Na	C	Unknown	50 Mg	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18314772	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3578406-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Cortisone			C				Not Reported
	Paracetamol			C				Not Reported
	Desoximetasone			C				Not Reported
	Gabapentin			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Reactine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18319569	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026178			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, 1 Every 1 Week		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Oral	25 Mg, 1 Every 1 Week		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, 1 Every 1 Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18319609	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026171			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200.0 Milligram, 2 Every 1 Day		Not Reported
	Celecoxib			S	Oral	200.0 Milligram, 2 Every 1 Day		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Toradol	S	Unknown	Unk		Not Reported
Tramadol	C	Unknown	100.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18319616	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026172			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Uveitis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S				Not Reported
	Humira			S	Subcutaneous	40 Mg 1 Every 1 Weeks		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported

	Prednisone		C	Unknown	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320038	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832105		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastroenteritis; Hepatitis; Nausea	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320057	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA026909			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Milligram, 1 Every 1 Day		Not Reported
	Indometacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	25.0 Milligram, 1 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	S	Oral	1.0 Gram, 2 Every 1 Day		Not Reported
Cymbalta	C	Oral	30.0 Milligram, 1 Every 1 Day		Not Reported
Folic Acid	C	Oral	1 Every 1 Week		Not Reported
Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320074	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832203		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Toradol			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320075	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027421			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Rituximab (Unknown)	S	Intravenous drip		Not Reported
	Actemra	S	Topical		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Subcutaneous	1.0 Mg	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500.0 Mg	Not Reported
	Topicort [Desoximetasone]	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320102	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027471			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Mg		Not Reported

Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	1000.0 Mg	Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400.0 Mg	Not Reported
	Lyrica	S	Unknown	150.0 Mg	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	1000.0 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown	3000.0 Mg, Qd (1 Every 1 Days)	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	40.0 Mg, 1 Every 1 Days	Not Reported
	Esomeprazole Sodium	C	Unknown		Not Reported
	Lumigan Rc	C	Ophthalmic	Unk, 1 Every 1 Days	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown	10.0 Mg, 1 Every 1 Days	Not Reported
	Trazodone	C	Unknown	200.0 Mg, 1 Every 1 Days	Not Reported
	Valsartan	C	Unknown	Unk, 1 Every 1 Days	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Wellbutrin Xl	C	Unknown	300.0 Mg, 1 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320112	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027409			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituximab (Unknown)		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Varicella Zoster Vaccine Live		S	Subcutaneous		Not Reported
	Desoximetasone		C	Oral		Not Reported
	Diclofenac		C	Unknown	100 Mg	Not Reported
	Xeljanz		C	Oral	5 Milliliter, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320131	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027396			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Week		Not Reported
	Naproxen			S	Unknown	500 Milligram, 2 Every 1 Day		Not Reported
	Orencia			S	Subcutaneous	150 Milligram, 1 Every 1		Not Reported

				Month	
Simponi	S	Subcutaneous	50 Milligram, 1 Every 1 Month		Not Reported
Sulfasalazine	S	Unknown	500 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320172	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027207			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Diarrhoea; Heart Rate Increased; Hypertensive Crisis; Nausea; Pneumonia; Pneumonitis; Vomiting	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Oral	50 Mg		Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Prednisone			C				Not Reported
	Tylenol			C	Oral	650 Mg		Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320174	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1832216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis;	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Shoulder Arthroplasty	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Viread	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320176	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320180	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA027352			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320193	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027332			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1 Every 1 Day		Not Reported

Methotrexate	S	Unknown	20 Mg, 1 Every 1 Week		Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg		Not Reported
Bupropion	C	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320194	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027339			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320208	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027345			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320214	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027451			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituximab (Unknown)			S	Intravenous drip	2000 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	750 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Days		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320220	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027433			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral	22.5 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Parenteral	25.0 Milligram		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk, 1 Every 1 Weeks		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			C	Unknown	Unk, 1 Every 1 Days		Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Minocycline			C	Unknown			Not Reported
	Penicillamine			C	Unknown			Not Reported

Prednisolone	C	Unknown	Unk		Not Reported
Prednisolone	C	Unknown	6.0 Milligram, 1 Every 12 Hours		Not Reported
Tocilizumab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320227	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027509			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported
	Diclofenac			C	Oral	100.0 Milligram		Not Reported
	Xeljanz			C	Oral	5.0 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320238	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027452			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Rituximab (Unknown)			S	Intravenous (not			Not Reported

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Factor Positive			otherwise specified)			
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Arthrotec	C	Unknown			Not Reported
	Azathioprine	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Gold	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320257	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027842			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg		Not Reported
	Leflunomide			S	Unknown	10.0 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	15.0 Mg		Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320298	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832009			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320328	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2020-CA-1832173		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Leflunomide			S	Oral			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Minocycline Hydrochloride	S	Unknown	Actavis
	Oxycodone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

	Xeljanz	S	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320461	EXPEDITED (15-DAY)		HO, LT	ES-ROCHE-2680968		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19; Off Label Use; Pancytopenia; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Day 0 And Day 4, Reduced To 500 Mg/12 Hours		Not Reported
	Prednisone			S	Unknown			Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	1 G, 3x Per Day		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	600 Mg, 2x Per Day		Not Reported
	Azithromycin Dihydrate			S	Unknown	250 Mg, Per Day		Not Reported
	Azithromycin Dihydrate			S	Unknown	500 Mg, Per Day		Not Reported
	Paracetamol			S	Unknown	1 G		Not Reported
	Basiliximab			S	Unknown	Day 0 And Day 4		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x Per Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 2x Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320485	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026963			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	25 Mg, 2 Every 1 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320610	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA027431			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral	10.0 Milligram		Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	400.0 Milligram 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200.0 Milligram 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400.0 Milligram 1 Every 2 Weeks		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram 2 Every 1 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram 2 Every 1 Days		Not Reported
	Leflunomide			S	Oral	10.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram 1 Every 1 Weeks		Not Reported

Orencia	S	Unknown		Not Reported
Plaquenil	S	Unknown	200.0 Milligram 2 Every 1 Days	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Amlodipine	C	Unknown		Not Reported
Arava	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown	5.0 Milligram 2 Every 1 Days	Not Reported
Viread	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320635	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA027667			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Synovitis; White Blood Cell Count Decreased	Rituximab (Unknown)			S	Unknown	Solution For Injection		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg 2 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg		Not Reported

	Hydroxychloroquine		S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Mg	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	400 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	400 Mg	Not Reported
	Remicade		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320719	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027717			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Rituximab (Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram		Not Reported
	Leflunomide			S	Unknown	10.0 Milligram, 1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	15.0 Milligram		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320941	EXPEDITED (15-DAY)		OT	CA-ACCORD-202895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Lyrica			S	Oral	2 Every 1 Days		Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320973	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026245			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Headache; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Prescribed Overdose; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Thyroid Neoplasm; Toxicity To Various Agents; Treatment	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1 Every 1 Days		Not Reported
	Apo-Leflunomide			S	Oral	10 Mg		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Arava			S	Unknown	50 Mg		Not Reported
	Arava			S	Unknown	10 Mg		Not Reported
	Celebrex			S	Unknown	50 Mg, 1 Every 1 Weeks		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Weeks		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg		Not Reported

Failure	Hydroxychloroquine Sulfate	S	Unknown	300 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1 Every 1 Days	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Leflunomide	S	Oral	20 Mg	Not Reported
	Leflunomide	S	Oral	10 Mg	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg	Not Reported
	Methotrexate	S	Subcutaneous	2.5 Mg	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown	2 Mg, 1 Every 1 Days	Not Reported
	Sulfasalazine	S			Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18320976	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026244			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Inflammation; Interstitial Lung Disease; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Pneumonia; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2 Every 1 Days	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram 1 Every 2 Weeks	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	17 Milligram, 1 Every 1 Weeks	Not Reported
	Naproxen	S	Unknown		Not Reported
	Naproxen	S	Unknown	500 Milligram, 1 Every 1 Days	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, 1 Every 4 Weeks	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Remicade	S	Subcutaneous	500 Milligram	Not Reported
	Remicade	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown	2 Milligram	Not Reported
	Sulfasalazine	S			Not Reported
	Allopurinol	C	Unknown		Not Reported
	Atorvastatin Calcium	C	Unknown		Not Reported

Bisoprolol	C	Unknown		Not Reported
Digoxin	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Nifedipine	C	Unknown		Not Reported
Palafer	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Prednisone	C	Unknown	5 Milligram, 1 Every 1 Day	Not Reported
Prednisone	C			Not Reported
Prednisone	C	Unknown	10 Milligram, 1 Every 1 Days	Not Reported
Prednisone	C			Not Reported
Rabeprazole Sodium	C	Unknown	20 Milligram, 1 Every 1 Days	Not Reported
Synthroid	C	Unknown		Not Reported
Toloxin [Digoxin]	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Xarelto	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days	Not Reported
Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days	Not Reported
Zinc Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321001	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026283			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis;	Rituximab (Unknown)			S	Intravenous (not			Not Reported

Off Label Use; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal			otherwise specified)			
	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra	S	Unknown			Not Reported
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Methotrexate	S	Unknown	25 Milligram		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321051	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2020CA026042			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321400	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-18418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Unknown	Unknown		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unknown		Not Reported
	Cefixime			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Morphine Hydrochloride			S	Unknown	Unknown		Not Reported
	Nifedipine			S	Unknown	Unknown		Not Reported
	Pantoprazole			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rivotril			S	Unknown	Unknown		Not Reported
	Zantac			S	Unknown	Unknown		Not Reported
	Zopiclone			S	Unknown	Unknown		Not Reported
	Morphine Sulfate			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321404	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026928			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint	Rituximab (Unknown)			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	22.5 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Parenteral	25.0 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Actemra	C	Unknown		Not Reported
	Azathioprine	C	Unknown	1 Every 1 Days	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Prednisone	C	Unknown	6 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321419	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-29607			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	Unknown		Not Reported
	Atorvastatin Calcium	C	Unknown	Unknown		Not Reported
	Pantoprazole	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321558	EXPEDITED (15-DAY)		OT	CA-ACCORD-202663		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever;	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Alendronate Sodium/Alendronic Acid			S				Accord
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cetirizine			S				Not Reported
	Cimzia			S				Not Reported
	Cortisone			S				Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus			otherwise specified)		
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Xeljanz	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Cimzia	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321575	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017611			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective	Azathioprine			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321597	EXPEDITED (15-DAY)		OT	IT-LUPIN		64 YR	Unknown	ITA

PHARMACEUTICALS INC.-2020-06517

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk, Qd		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Milligram, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321628	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram (2 Every 1 Days)		Not Reported
	Enbrel			S	Unknown	50 Milligram (1 Every 1 Weeks)		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram (2 Every 1 Days)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram (2 Every 1 Days)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram (2 Every 1 Days)		Not Reported
	Methotrexate			S	Oral	17.5 Milligram (1 Every 1 Weeks)		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321711	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027080			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Arava			S	Unknown	20.0 Milligram, 1 Every 1 Day		Not Reported
	Enbrel			S	Unknown	50.0 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, 1 Every 1 Week		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321871	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027133			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Mefenamic Acid	C			Not Reported
	Prednisone	C	Oral	6 Mg, 1 Every 24 Hours	Not Reported
	Prednisone	C	Oral	6 Mg, 1 Every 24 Hours	Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321916	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-06522		91 DAY	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S	Unknown	6.5 Milligram/Kilogram, Qd		Lupin
	Levetiracetam			C	Intracardiac	28 Milligram/Kilogram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18321946	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027248			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25.0 Milligram, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, 2 Every 1 Days		Not Reported
	Leflunomide			S	Oral	20.0 Milligram, 1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	20.0 Milligram, 1 Every 1		Not Reported

				Weeks	
	Methotrexate	S	Unknown	15.0 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300.0 Milligram, 1 Every 6 Weeks	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322074	EXPEDITED (15-DAY)		DS	CA-ACCORD-202806		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S				Accord
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322075	EXPEDITED (15-DAY)		OT	CA-ACCORD-202900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased;	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Accord

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra	S	Unknown			Not Reported
	Ciclosporin	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown	1 Every 2 Weeks		Not Reported
	Orencia	S	Unknown	1 Every 1 Weeks		Not Reported
	Rituximab	S	Intravenous drip			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tofacitinib	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322076	EXPEDITED (15-DAY)		HO	CA-ACCORD-202916			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322085	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027367			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Synovitis	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram (1 Every 1 Weeks)		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram (1 Every 12 Hours)		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram (1 Every 12 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322148	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027651			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Simponi		C	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322203	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06529		58 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported
	Mometasone Furoate			C	Topical	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322234	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027134			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituximab (Unknown)			S	Intravenous drip	2000 Mg		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Subcutaneous	750 Mg, 1 Every 1 Weeks		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322236	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-249077			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Drug Interaction	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun
	Lopinavir/Ritonavir			S	Oral	400/100 Mg, Bid		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	10 Milligram		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322296	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077246		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			C	Intravenous (not	Unk		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322319	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027215			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322326	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-29650		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Infliximab	S	Unknown	Unknown		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Prednisone	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322610	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-262600		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Product Effect Incomplete; Urticaria	Azithromycin			S	Unknown	Unk		Sun
	Cetirizine			S	Unknown	10 Milligram, Bid		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Oseltamivir			S	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Irbesartan/Hydrochlorothiazide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322626	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-262356		91 DAY	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Levetiracetam			S	Unknown	28 Milligram/Kilogram, Daily		Sun

	Hydroxychloroquine	S	Unknown	6.5 Milligram/Kilogram, Daily		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322769	EXPEDITED (15-DAY)		HO, OT	IE-ACCORD-202990		57 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glucose-6-Phosphate Dehydrogenase Deficiency; Haemolytic Anaemia; Off Label Use	Hydroxychloroquine			S				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322891	EXPEDITED (15-DAY)		OT	CA-ACCORD-202896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323048	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA026705			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported

Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Rituximab (Unknown)	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Gold	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Ilaris	C	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323079	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077285		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram One Every One Day		Not Reported
	Arava			S	Oral	20 Milligram, One Every One Day		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S		400 Milligram, One Every One Day	Not Reported
	Indocid [Indometacin]	S	Unknown	Unk	Not Reported
	Indomethacin [Indometacin]	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram One Every One Day	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, One Every One Week	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, One Every One Day	Not Reported
	Prednisone	S	Oral	25 Milligram, One Every One Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Milligram. Two Every One Day	Not Reported
	Cymbalta	C	Oral	30 Milligram, One Every One Day	Not Reported
	Folic Acid	C	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Every One Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323124	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-261941		47 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Urticarial Vasculitis	Ceftriaxone		S	Unknown	Unk	Not Reported
	Enoxaparin Sodium		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Sun
	Lopinavir/Ritonavir		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323207	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832341		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Asa			C				Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Paroxetine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Risedronate	C	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Simvastatin	C	Unknown		Not Reported
	Statex /00036302/	C	Unknown		Not Reported
	Telmisartan	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323223	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026750			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Rituximab (Unknown)			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1 Every 24 Hours		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk, 1 Every 1 Week		Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323332	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832410		25 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Chest Discomfort; Cutaneous T-Cell Lymphoma; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Latent Tuberculosis; Off Label Use; Pain; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Tenosynovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Calcium Carbonate			C				Not Reported
	Folic Acid			C				Not Reported
	Omega-3			C				Not Reported
	Vitamin D3			C	Oral	1000 Iu (International Unit) Daily;		Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323458	EXPEDITED (15-DAY)		OT	CA-ACCORD-202660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial	Also Received Oral		Accord
	Alendronate Sodium/Alendronic Acid			S	Oral			Accord
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported

Diclofenac	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown	Also Received 5.0 Mg	Not Reported
Orencia	S	Subcutaneous	Also Received Intravenous (Not Otherwise Specified)	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Pseudoephedrine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323479	EXPEDITED (15-DAY)		OT	CA-ACCORD-203096		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial Neuralgia; Fatigue; Groin Pain; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness;	Atorvastatin/Atorvastatin Calcium			S	Unknown	1 Every 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Bisoprolol			S	Unknown	2 Every 1 Days		Not Reported
	Sandostatin			S	Subcutaneous			Not Reported
	Dapagliflozin			C	Unknown	1 Every 1 Days		Not Reported
	Sandostatin			S	Intramuscular	1 Every 1 Months		Not Reported

Labyrinthitis; Muscle Spasms; Nausea; Rheumatoid Arthritis; Visual Impairment; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323506	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026807			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Mg, 1 Every 1 Week		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Gold			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323856	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026835			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Therapeutic Product Effect Decreased	Enbrel	S	Unknown	1.0 Dosage Form, 1 Every 1 Week	Not Reported
	Enbrel	S	Subcutaneous	1.0 Dosage Form, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Acetaminophen	C			Not Reported
	Arava	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Days	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323905	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1832476		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Naproxen Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323958	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832754		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Acetaminophen	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832156		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

	Sulfasalazine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324067	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-20_00010999		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Product Use Issue; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Brenzys			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324069	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832334		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Arthroplasty; Arthralgia; Drug Ineffective; Hip Arthroplasty; Knee Arthroplasty; Pain In Extremity; Peripheral Swelling; Psoriasis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold Radioactive Colloidal			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324088	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026952			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Therapeutic Product Effect Decreased	Rituximab (Unknown)	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Lyrica	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral	5.0 Milligram, 2 Every 1 Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324623	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026990			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Device Occlusion; Drug Ineffective; Gallbladder Disorder; Headache; Heart Rate Decreased; Hypertension; Infusion Related Reaction; Migraine; Nausea; Off Label Use; Pharyngeal Paraesthesia	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	500.0 Milligram		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000.0 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650.0 Milligram		Not Reported
	Benadryl			C	Oral	50 Milligram		Not Reported
	Diphenhydramine			C	Oral	50.0 Milligram		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Solumedrol			C	Intravenous (not	100.0 Milligram		Not Reported

			otherwise specified)			
	Tylenol	C	Oral	650.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324713	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA026937			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Rituximab (Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, 1 Every 1 Days		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324737	EXPEDITED (15-DAY)		OT	CA-ACCORD-202914			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Accord
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Abatacept			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Prednisone	C	Oral	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324842	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020370612		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Drug Ineffective; Panniculitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324960	NON-EXPEDITED			US-PFIZER INC-2020371186		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysgeusia; Pain In Extremity; Swelling	Xeljanz Xr			S	Oral	11 Mg, 1x/Day (Take 1 Tablet By Mouth Once Daily)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325051	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077708			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actemra			C	Subcutaneous	162 Milligram, Qwk		Not Reported
	Arava			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325054	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027337			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Stress	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Form, 1 Every 1 Week		Not Reported

Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Advil [Ibuprofen]	C	Unknown		Not Reported
Mefenamic Acid	C	Unknown		Not Reported
Prednisone	C	Oral	6.0 Milligram, 1 Every 1 Day	Not Reported
Prednisone	C	Oral	10.0 Milligram, 1 Every 1 Day	Not Reported
Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325056	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077693			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325065	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077744		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325090	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-06502		64 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (Gavage)		Lupin
	Ceftriaxone			S	Intravenous (not	Unk		Lupin

			otherwise specified)			
	Clindamycin	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Lopinavir/Ritonavir	C	Unknown	400/100 Mg, Qd (Gavage)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325161	EXPEDITED (15-DAY)		DS, OT	CA-SAKK-2020SA250519AA			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Maternal Exposure During Pregnancy; Muscle Injury; Nasopharyngitis; Pain;	Topicort			S	Cutaneous	Unk		Sanofi
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi
	Prednisone			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg		Sanofi
	Chlorhexidine Salt Not Specified			S		Unk		Not Reported
	Chlorhexidine Salt Not Specified			S	Topical	Unk		Not Reported
	Chlorhexidine Gluconate			S		Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd (1 In 1 Day)		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw (1 In 1 Week)		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Oxycodone			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported

Pemphigus; Pericarditis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Chlorhexidine Gluconate	S	Buccal	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg	Sanofi
	Prednisone	S	Oral	7.5 Mg	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Oral	2000 Mg	Not Reported
	Sulfamethoxazole/Trimethoprim	C		Unk	Not Reported
	Acetaminophen	S		Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	2912 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	3011.2 Mg	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Cetirizine	S		10 Mg	Not Reported
	Cetirizine	S		10 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone Terephthalate	S		Unk	Not Reported
	Oxycodone And Acetaminophen	S		Unk	Not Reported
	Pseudoephedrine	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Mg Cyclical	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfamethoxazole	S		Unk	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Sulfathalidine	S	Oral	2000 Mg	Not Reported
	Sulfathalidine	S	Oral	500 Mg	Not Reported
	Xeljanz	S		10 Mg	Not Reported
	Xeljanz	S		10 Mg	Not Reported
	Atasol [Paracetamol]	C		Unk	Not Reported
	Cetirizine	C		Unk	Not Reported
	Desogestrel & Ethinyl Estradiol	C		Unk	Not Reported
	Ibuprofen	C		Unk	Not Reported
	Pantoloc [Pantoprazole]	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Salazopyrin	C		Unk	Not Reported
	Tylenol	C		Unk	Not Reported
	Tylenol With Codeine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325192	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1832148		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily	Prednisone			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Arava	S	Oral	200 Milligram Daily;	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325217	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1832478		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Back Pain; Body Height Decreased; C-Reactive Protein Decreased; Deep Vein Thrombosis; Depression; Drug Ineffective; Drug Ineffective; Emotional Distress; Emotional Distress; Fatigue; Foot Fracture; Malaise;	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

Osteoporosis; Pelvic Fracture; Pruritus Allergic; Psoriasis; Psoriatic Arthropathy; Quality Of Life Decreased; Rheumatoid Arthritis; Sensitivity To Weather Change; Spinal Fracture	Plaquenil	S	Unknown			Not Reported
	Methotrexate	C	Oral			Not Reported
	Tofacitinib Citrate	C		10 Milligram Daily;		Not Reported
	Vioxx	C				Not Reported
	Warfarin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325222	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1832255		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	1 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Rectal	2 Gram Daily;		Not Reported
	Hydroxychloroquine/00072603/			C				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325323	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020372947		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Xeljanz			S		5 Mg		Pfizer

Mixed Connective Tissue Disease; Musculoskeletal Pain	Methotrexate Sodium		S	Unk	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325492	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1832541		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325493	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832066		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis;	Doxycycline Hyclate			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported

Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Synovitis; Terminal State; Thrombosis	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325642	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral	1 Gram		Not Reported
	Prednisone			C	Oral	5 Milligram		Not Reported

	Prednisone		C	Oral	10 Milligram	Not Reported
	Simponi		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325645	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077833		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Migraine; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil S			S	Oral			Not Reported
	Remicade			S	Intracavernous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325699	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2020372170		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Maternal Exposure Before Pregnancy	Methotrexate Sodium			S		20 Mg (3 Years Ago)		Pfizer
	Quensyl			S		Unk (3 Years Ago)		Not Reported
	Folsan			C		5 Mg (3 Years Ago)		Not Reported
	Prednisolone			C		2.5 Mg (3 Years Ago)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325851	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1082381		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Cardiac Failure; Cardiomyopathy; Mitral Valve Incompetence; Myocardial Fibrosis; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	600 Milligram, Qd		Mylan
	Methotrexate			C	Unknown			Mylan
	Adalimumab			C	Unknown			Mylan
	Abatacept			C	Unknown			Mylan
	Lansoprazole			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18325874	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1833051		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Sepsis; Drug Ineffective; Hypotension; Off Label Use; Septic Shock	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Epoprostenol			S	Respiratory (inhalation)	She Was Treated For 4 Days With Inhaled Epoprostenol.		Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Levofloxacin			C				Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18326020	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1833061		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18326046	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077684		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Back Pain; Body Height Decreased; C-Reactive Protein Decreased; Deep Vein Thrombosis; Depression; Drug Ineffective; Emotional Distress; Fatigue; Foot Fracture; Malaise; Osteoporosis; Pelvic Fracture; Pruritus Allergic; Psoriasis; Psoriatic Arthropathy; Quality Of Life Decreased; Rheumatoid Arthritis; Sensitivity To Weather Change; Spinal Fracture	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Dilaudid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported
	Tofacitinib Citrate			C	Unknown	5 Milligram, Bid		Not Reported
	Vioxx			C	Unknown	Unk		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18326387	EXPEDITED (15-DAY)		OT	NVSC2020FR262986			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg (On Day 1)		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18326576	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077702		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Astigmatism; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Orencia		S	Unknown	Unk	Bristol Myers Squibb
	Actemra		S	Unknown	Unk	Not Reported
	Baclofen		S	Unknown	10 Milligram	Not Reported
	Baclofen		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Unknown	Unk Unk, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Naproxen		S	Oral	500 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S			Not Reported
	Sulfadiazine		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18326602	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3581481-00		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia Viral	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18326815	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1832795		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Oral		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Oral	2000 Milligram Daily;	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;	Not Reported
Topicorten	S	Cutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18326938	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832230		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Intolerance; Neck Pain; Neck Surgery; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Arava		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Mobicox		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18327043	NON-EXPEDITED			NVSC2020US263161			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18327053	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832569		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased;	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram Daily;		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine			S	Unknown			Not Reported

Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Hydrochloride				
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Topicorten	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Leflunomide	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18327531	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200823608			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Thalidomide			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18327949	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027362			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18327957	EXPEDITED (15-DAY)		DS	CA-CELLTRION INC.-2020CA027331			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Calcium			C				Not Reported
	Duloxetine Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18327966	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027398			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Weight Decreased	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18328056	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027411			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Desoximetasone			C	Unknown	10 Milligram, 1 Every 1		Not Reported

				Days	
	Diclofenac	C	Unknown	100 Milligram, 1 Every 1 Days	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Voltaren [Diclofenac]	C	Unknown	100 Milligram, 1 Every 1 Days	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zostavax	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	11374404	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014100327		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Bid		Not Reported
	Humira			S	Unknown	40 Milligram, 2 Times/Wk		Not Reported
	Orencia			S	Subcutaneous	750 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	750 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Other	Unk		Not Reported

Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	2000 Milligram	Not Reported
Imuran	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
Xeljanz	S	Oral	Unk, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
Xeljanz	S	Oral	5 Megabecquerel, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	Unk, 2 Times/Wk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Tofacitinib	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	12331166	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054169		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel	S	Unknown	Unk	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Kineret	S	Subcutaneous	100 Mg, Unk	Not Reported
	Gold	S	Other	Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Actonel	S	Oral	35 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported

Leflunomide	S	Oral	20 Mg, Qd		Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qh		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Risedronate Sodium	S	Unknown	Unk		Not Reported
Risedronate Sodium	S	Oral	35 Milligram, Qwk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qh		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Qwk		Not Reported
Risedronate	C	Unknown	35 Milligram, Qwk		Not Reported
Prednisone	C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	12702020	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1482		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intra-arterial			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Thrombosis; Urticaria	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Single Use Vial	Not Reported
	Ilaris	S	Unknown		Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Kineret	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Marijuana	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Apo-Sulfasalazine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Lyrica	C	Oral	Not Reported
Rituximab	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	12913683	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092891		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	25 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk, Prn	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Unknown	5 Milligram	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Dosage Form	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported

Folic Acid	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Folic Acid	S	Unknown	0.5 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Intra-arterial	25 Milligram, Qwk	Not Reported

Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Apo Folic	S	Unknown	5 Milligram	Not Reported
Apo Prednison	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported

Sulfate]				
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Topicort [Hydrocortisone	S	Cutaneous	Unk	Not Reported

Acetate]				
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Cortisone	S	Topical	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Topicort Lp	S	Unknown	Unk	Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Apo-Folic Acid	S	Unknown	1 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13058810	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015763		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide	S	Oral	Unk	Apotex
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13145122	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016393950		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Pfizer
	Folic Acid			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Ramipril			S	Unknown	1 Dosage Form, Qd		Pfizer
	Ramipril			S	Unknown	Unk, Unk, Qd		Pfizer
	Altace			S	Unknown	1 Dosage Form, Qd		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	600 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine Phosphate	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, 1x/Day (Daily)	Not Reported
Levothyroxine Sodium	S	Unknown	Unk Unk, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Cosopt	S	Unknown	Unk, 2x/Day	Not Reported
Levothyroxine	S	Unknown	1 Df, 1x/Day	Not Reported
Levothyroxine	S	Unknown	Unk	Not Reported
Prednisone	S		7 Milligram, Qd	Not Reported
Prednisone	S		Unk Unk, Qd	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	2 Df, 2x/Day	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Unk Unk, 2x/Day	Not Reported

Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Daily	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Tylenol No.2	C		Unk	Not Reported
Acetaminophen	C	Oral	1000 Milligram	Not Reported
Acetaminophen	C	Oral	1000 Milligram	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Hydroxychloroquine Phosphate	C		Unk	Not Reported
Caffeine	C		Unk	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Unk	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Meprobamate	C		Unk	Not Reported
Phosphate	C		Unk	Not Reported
Timolol Maleate	C	Unknown	2 Dosage Form, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13147266	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005239		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not	Unk		Not Reported

Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Milligram, Bid	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Toradol	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
	Prednisone	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	100 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13251448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Cyclosporine			S				Apotex
	Apo-Azathioprine			S	Oral	Unk		Not Reported
	Apo-Azathioprine			S				Not Reported
	Cyclosporine			S	Subcutaneous	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	640 Mg, Q.Wk.	Not Reported
Actemra	S	Unknown	640 Mg, One Every 4 Weeks	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S			Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	50 Milligram	Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	400 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
Humira	S	Subcutaneous	Unk, Q.Wk.	Not Reported
Imuran /00001501/	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S			Not Reported

Tocilizumab	S	Unknown	640 Mg, Q.Wk.		Not Reported
Tocilizumab	S				Not Reported
Certolizumab Pegol	S	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13362332	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Ramipril			S	Unknown	Unk Unk, Bid		Apotex
	Ramipril			S	Oral	Unk, Qd		Apotex
	Ramipril			S	Oral	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Dorzolamide ,Timolol			S	Unknown	Unk Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	1 Df, Bid		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Levothyroxine			S	Unknown	1 Df, Unk		Not Reported
	Levothyroxine			S	Unknown	Unk Unk, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13852885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Intra-arterial	25 Mg, Qwk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

	Xeljanz	S	Unknown			Not Reported
	Diclofenac Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13957994	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017733		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q.M.T.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Penicillamine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported

Doxycycline	C	Unknown	Unk		Not Reported
Elavil /00002202/	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Tobramycin	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	13975158	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	640 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	400 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	14128207	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020228		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Naproxen			C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	14505012	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007258		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram, Qd		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	10 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Sarilumab	S	Unknown		Not Reported
Acetaminophen	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported
Golimumab	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Leflunomide	C	Unknown		Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	14599594	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP007040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1.5 G, Bid		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	15042251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006898		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Oral			Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Naproxen	C	Unknown	500 Mg, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	15531784	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2949		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Product Use Issue; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Penicillin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

	Plaquenil	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	15639542	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-106082		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Q2wk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Penicillamine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Etanercept	S	Subcutaneous	25 Milligram, 2 Times/Wk	Not Reported
Imuran [Azathioprine Sodium]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Milligram	Not Reported
Leflunomide	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Azathioprine	C	Oral	200 Milligram, Qd	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
Docusate Sodium	C	Oral	100 Milligram, Qd	Not Reported
Doxycycline	C	Oral	Unk, 2 Every Day	Not Reported
Elavil [Allopurinol]	C	Oral	Unk, Qd	Not Reported
Prednisone	C	Oral	8 Mg, Qd	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Oral	1.5 Gram, Bid	Not Reported
Tobramycin	C	Unknown	0.3 Percent, Qid	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	15640647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Intentional	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia		S	Subcutaneous		Not Reported
	Cortisone		S	Oral		Not Reported
	Desoximetasone		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Oral		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown	400 Mg, Qd	Not Reported
	Prednisone		S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral	1 G, Bid	Not Reported
	Tofacitinib Citrate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	15964311	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013565		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	20 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	20 Milligram, Qwk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	16075887	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019352			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Dosage Form		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Twice Weekly		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q.O.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Imuran /00001501/	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported
Plaquenil /00072602/	S	Unknown	200 Dosage Form		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Acetylsalicylic Acid	C	Unknown	81 Milligram, Qd		Not Reported
Tiaprofenic Acid	C	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	16481798	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1203		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Medication Error; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Every 2 Week (Cyclical)		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Gold	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Subcutaneous	Not Reported

Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Bifidobacterium Bifidum	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	16543085	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022600		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Rheumatoid Arthritis	Azathioprine			S	Unknown	100 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Meloxicam			S	Unknown	15 Milligram, Qd		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	25 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin			C	Unknown	20 Mg, Qd		Not Reported

Gabapentin	C	Unknown	100 Mg, Qd		Not Reported
Lansoprazole	C	Unknown	30 Milligram, Qd		Not Reported
Symbicort Tu	C	Unknown	Unk		Not Reported
Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Plaquenil /00072602/	C	Endocervical	Unk		Not Reported
Budesonide;Formoterol Fumarate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	16820420	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17157820	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025989		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin			S	Unknown	Unk		Apotex
	Metformin			S				Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported
	Imuran /00001501/			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17241012	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2019AP026871		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased;	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Abatacept	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Etanercept	S	Unknown	15 Milligram	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	15 Mg, Q.O.Wk.	Not Reported
	Enbrel	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Infliximab	S	Unknown	200 Mg, Q.M.T.	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Q.Wk.	Not Reported
	Infliximab	S	Unknown	200 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	420 Mg, Unk	Not Reported
	Rituximab	S	Unknown	420 Milligram, Q.M.T.	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tocilizumab	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17242060	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026872		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity; Hypersensitivity Vasculitis; Hypertension; Limb Discomfort; Musculoskeletal Stiffness; Nausea; Oedema Peripheral; Off Label Use; Petechiae; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Colchicine			S				Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Coversyl /00790702/			C	Unknown	Unk		Not Reported
	Hctz			C	Unknown	Unk		Not Reported
	Hydrochlorothiazide			C	Endocervical	Unk		Not Reported
	Leucovorin /00566701/			C	Oral	5 Mg, Q.Wk.		Not Reported
	Leucovorin /00566701/			C	Unknown	Unk		Not Reported
	Ranitidine			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Intramuscular	12.5 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

	Levothyroxine Sodium	C	Unknown	Unk	Not Reported
	Colchicine	C	Unknown	Unk	Not Reported
	Coversyl [Perindopril Arginine]	C	Unknown	Unk	Not Reported
	Calcium Folinate	C	Oral	5 Milligram, Q.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17362094	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17422934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009905		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Naproxen	C	Unknown	500 Milligram, Qd	Not Reported
Arava	S	Unknown		Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Bisoprolol	C	Unknown		Not Reported
Digoxin	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Nifedipine	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Toloxin [Digoxin]	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Xarelto	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17491286	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008190		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling;	Leflunomide			S	Unknown	Unk, Unknown		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk, Unknown		Not Reported

Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Plaquenil /00072602/		S	Unknown	400 Mg, Qd	Not Reported
	Rituxan		S	Unknown	Unk, Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk, Unknown	Not Reported
	Sulfasalazine		S	Unknown	1 G, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17620210	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009225		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cataract; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Off Label Use; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Sulfasalazine			S	Unknown	750 Mg, Qd		Not Reported
	Hydrochlorothiazide W/Lisinopril			C	Unknown	Unk		Not Reported
	Hydrochlorothiazide W/Lisinopril Dihydrate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Rituxan			C	Unknown	Unk		Not Reported
	Tylenol Extra Strength			C	Unknown	Unk		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz Xr			C	Oral	5 Milligram, Bid		Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17824262	EXPEDITED (15-DAY)		OT	NVSC2020US141645			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastrointestinal Disorder; Therapeutic Product Effect Decreased; Uterine Leiomyoma	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17915893	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-046715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			C	Unknown	25 Milligram		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Qmo		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	17975636	EXPEDITED (15-DAY)		LT, OT	NVSC2020FR185417		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure Congestive; Pulmonary Embolism	Furosemide			S	Oral	40 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Heparin Sodium			C	Intravenous (not otherwise specified)	Unk (25000 (Units Not Specified), Qd)		Not Reported
	Enoxaparin			C	Subcutaneous	4000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18000395	EXPEDITED (15-DAY)		HO, OT	NVSC2020DE191885		62 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Covid-19; Exercise Tolerance Decreased; Leukopenia; Lymphopenia; Off Label Use; Oropharyngeal Pain; Pyrexia; Rhinorrhoea; Tachycardia	Mycophenolate Mofetil			S	Unknown	500 Mg, Q12h		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk, Dose Reduced		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Cyclosporine			S	Unknown	135 Plus/Minus 30 Ng/Ml		Not Reported
	Cyclosporine			S	Unknown	Unk, Dose Reduced		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Q12h		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Q12h		Not Reported
	Valganciclovir			C	Unknown	Unk		Not Reported
	Ganciclovir			C	Unknown	Unk		Not Reported
	Cotrimoxazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18005738	EXPEDITED (15-DAY)		OT	NVSC2020IT180687		25 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Augmentin			S	Oral	1 G, Qd		Not Reported
	Clexane			C	Subcutaneous	1 Df, Qd		Not Reported
	Dicloreum			C	Intramuscular	Strength-75 Mg / 3 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18013440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054288		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	9 Milligram		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	200 Milligram		Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, 2 Every 1 Day		Not Reported
	Prednisone			S	Unknown	9.0 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Unknown	500 Milligram		Not Reported

Gabapentin	C	Unknown	600 Milligram, 3 Every 1 Day		Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	10 Milligram, Qd		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported
Dexamethasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18015364	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-055724			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1.2 Milliliter		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18017181	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-054706		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cosentyx			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18042935	EXPEDITED (15-DAY)		OT	CA-ACCORD-191109		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral	Not Specified		Accord
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S		Not Specified		Not Reported
	Leflunomide			S				Not Reported
	Prednisone			C	Oral	Not Specified		Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			C	Oral	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18045650	EXPEDITED (15-DAY)		OT	NVSC2020ES198120		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Disease Progression; Drug Ineffective; Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Imatinib			C	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18048306	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2020M1065097		62 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asymptomatic Covid-19; Cardiac Infection; Covid-19; Exercise Tolerance Decreased; Leukopenia; Lymphopenia; Nosocomial Infection; Off Label Use; Oropharyngeal Pain; Pyrexia; Rhinorrhoea; Sars-Cov-2 Test Positive; Tachycardia	Mycophenolate Mofetil			S		500 Milligram, Bid		Mylan
	Mycophenolate Mofetil			S		500 Mg, Bid		Mylan
	Ciclosporin			S		Unk Target Range 135 ± 30 Ng / Ml		Not Reported
	Ciclosporin			S		Target Range 135 +/- 30 Ng/Ml		Not Reported
	Prednisone			S		10 Mg, Qd		Mylan
	Prednisone			S		50 Mg		Mylan
	Prednisone			S		Unk		Mylan
	Prednisone			S		25 Mg		Mylan
	Hydroxychloroquine			S		Received Till Day 14		Mylan
	Hydroxychloroquine			S		Loading Dose From Day 7		Mylan
	Hydroxychloroquine			S				Mylan
	Ganciclovir			C		Unk		Mylan
	Valganciclovir			C		Unk		Mylan
	Valganciclovir			C				Mylan
	Cotrimoxazole			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18049603	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-057692		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18064129	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18065590	EXPEDITED (15-DAY)		OT	CA-ACCORD-191914		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18129470	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2017GSK100243		38 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident At Home; Chest Injury; Circumstance Or Information Capable Of Leading To Medication Error; Cough; Depression; Headache; Inappropriate Schedule Of Product	Benlysta			S		600 Mg, Unk		Glaxosmithkline
	Benlysta			S		600 Mg, Unk		Glaxosmithkline
	Benlysta			S		710 Mg		Glaxosmithkline
	Methotrexate			S		Unk		Glaxosmithkline
	Azathioprine			S		Unk		Glaxosmithkline

Administration; Influenza; Limb Injury; Malaise; Product Availability Issue; Product Dose Omission; Pyrexia; Thermal Burn; Tooth Extraction; Tooth Infection; Toothache; Underdose; Weight Decreased	Hydroxychloroquine Sulfate	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18150179	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016292		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Joint Range Of Motion Decreased; Joint Swelling; Mobility Decreased; Mood Swings; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18171793	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyneuropathy	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex

Methotrexate	C	Unknown	25 Milligram		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Orencia	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Q.12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18171835	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP016033		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Leflunomide			S	Unknown	20 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram		Apotex
	Methotrexate			S	Unknown	25 Milligram, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Q.Wk.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Etanercept			S	Unknown	50 Milligram, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Q.Wk.		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18173606	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Foot Deformity; Hand Deformity; Intentional	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex

Product Use Issue; Joint Swelling; Leukopenia; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Q.Wk.	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Q.Wk.	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Q.Wk.	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Solu-Medrol	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18174423	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP013055		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Contraindicated Product Administered; Diarrhoea;	Methotrexate			S	Unknown	25 Milligram, Q.Wk.		Not Reported
	Methotrexate			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Azathioprine			S	Oral	200 Milligram, Qd		Apotex
	Azathioprine			S	Unknown	Unk		Apotex

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Actemra	S	Subcutaneous	162 Milligram, Q.O.Wk.	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Q.Wk.	Not Reported
	Gold	S	Intramuscular	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Q.Wk.	Not Reported
	Penicillamine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Q.M.T.	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Etanercept	S	Subcutaneous	25 Milligram, B.I.Wk.	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Docusate Sodium	C	Oral	100 Milligram, Qd	Not Reported
	Doxycycline	C	Oral	Unk	Not Reported
	Elavil [Allopurinol]	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	8 Milligram, Qd	Not Reported
	Sulfasalazine	C	Oral	1.5 Gram, Bid	Not Reported
	Tobramycin	C	Intraocular	0.3 Percent, Qid	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18176305	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016288		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Actemra			S	Unknown	4 Milligram/Kilogram		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18176328	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016289		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Apotex
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	25 Milligram, B.I.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, One Every 6 Weeks		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18179442	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016179			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Drug	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Leflunomide		S	Unknown	20 Milligram	Apotex
	Enbrel		S	Subcutaneous	50 Milligram, Q.Wk.	Not Reported
	Humira		S	Subcutaneous	40 Milligram Cyclical	Not Reported
	Methotrexate Sodium		S	Unknown	20 Milligram	Not Reported
	Methotrexate Sodium		S	Unknown	20 Milligram	Not Reported
	Methotrexate Sodium		S	Unknown	20 Milligram	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	750 Milligram, Q.M.T.	Not Reported
	Sulfasalazine		S	Unknown	2 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18180175	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP016110		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Breast Cancer; Breast Cancer Stage Iii; Condition Aggravated; Depression; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Hand Deformity; Infection; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Off Label Use; Ovarian Cancer; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Unevaluable	Hydroxychloroquine			S	Unknown	200 Milligram, Q.Wk.		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q.O.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Event; Urticaria	Remicade		S	Unknown	Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]		C	Unknown	Unk	Not Reported
	Amlodipine		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Tofacitinib Citrate		C	Unknown	Unk	Not Reported
	Viread		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18183283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016134		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Hydroxychloroquine			S	Oral			Apotex
	Leflunomide			S	Oral	20 Milligram, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Q.O.Wk.		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Q.12h		Not Reported
	Leflunomide			S	Oral	20 Milligram, Q.O.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18225360	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016885		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Hydroxychloroquine			S	Unknown	Unk		Apotex

Leflunomide	S	Unknown	Unk		Apotex
Etanercept	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Methotrexate	C	Oral	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18226849	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016867			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Milligram		Apotex
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18233077	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide	S	Unknown	20 Milligram, Qd		Apotex
	Leflunomide	S	Unknown	10 Milligram		Apotex
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid		Apotex
	Methotrexate	S	Unknown	20 Milligram, Q.Wk.		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Cosentyx	S	Unknown	150 Milligram, Q.M.T.		Not Reported
	Humira	S	Unknown	400 Milligram		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Cymbalta	C	Oral	60 Milligram, Qd		Not Reported
	Esomeprazole Magnesium Trihydrate;Naproxen	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18234935	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	25 Milligram, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Hydroxychloroquine			C	Unknown	400 Milligram		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18235978	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Methotrexate			S	Unknown	25 Milligram, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18235979	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Grip Strength Decreased; Hepatitis; Pain	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Milligram		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Imuran [Azathioprine Sodium]			C	Unknown	Unk		Not Reported
	Indomethacin [Indometacin]			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18236000	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016962			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Apo-Leflunomide		S	Unknown	Unk	Apotex
	Hydroxychloroquine		S	Unknown	Unk	Apotex
	Methotrexate		S	Unknown	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18236001	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP016971			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	15 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18236878	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	200 Milligram, B.I.Wk.		Apotex
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Apotex
	Leflunomide			S	Unknown	20 Milligram, Q.Wk.		Apotex

Methotrexate	S	Unknown	20 Milligram, Q.Wk.		Not Reported
Methotrexate	S	Unknown	15 Milligram, Q.Wk.		Not Reported
Orencia	S	Unknown	125 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 6 Weeks		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Enbrel	S	Unknown	25 Milligram, Q.O.Wk.		Not Reported
Humira	S	Subcutaneous	40 Milligram, Q.O.Wk.		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18236938	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	20 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18238170	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017054			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Milligram, Qd		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	Unk Unk, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18238413	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017063		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate			S	Oral	20 Milligram, Q.Wk.		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (Therapy Duration: 365 Unit Unspecified)		Apotex
	Leflunomide			S	Unknown	10 Milligram, Qd		Apotex
	Simponi			S	Subcutaneous	50 Milligram, Q.M.T.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18239569	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017095			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Hydroxychloroquine			S	Unknown	200 Milligram		Apotex
	Leflunomide			S	Unknown	20 Milligram		Apotex
	Methotrexate			C	Unknown	Unk		Not Reported
	Tofacitinib			C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18241120	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Encephalitis; Meningitis; Synovitis; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	20 Milligram, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18242520	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP017174		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Milligram		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Milligram		Apotex
	Methotrexate			S	Unknown	1 Dosage Form, Q.Wk.		Not Reported
	Methotrexate			S				Not Reported
	Aclasta			S	Intravenous (not	Unk		Not Reported

Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection			otherwise specified)		
	Arava	S	Unknown	20 Milligram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 Gram, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Tramacet	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen W/Oxycodone	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported
	Depo-Medrol	C	Subcutaneous	Unk Unk, Q.M.T.	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	1 Milligram	Not Reported
	Lyrica	C	Oral	150 Milligram	Not Reported
	Metformin	C	Unknown	5 Milligram	Not Reported
	Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Q.M.T.	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	2 Dosage Form	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C			Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd	Not Reported

Nortriptyline Hydrochloride	C				Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Premarin	C	Unknown	0.625 Milligram		Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Q.Wk.		Not Reported
Vagifem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18246493	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020035204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Ucb
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Golimumab			S				Not Reported
	Humira			S		400 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Sarilumab			S				Not Reported

Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Xeljanz	S		10 Milligram	Not Reported
Alendronate Sodium;Alendronic Acid	S	Oral		Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Subcutaneous		Not Reported
Diclofenac	S		50 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Folic Acid	S		1 Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Prednisone	S		40 Milligram	Not Reported
Prednisone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S		500 Mg	Not Reported
Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Sulfasalazine	S	Oral	1 Gram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Unk	Not Reported

Topicort [Desoximetasone]	S	Topical	Unk		Not Reported
Apo Prednison	S				Not Reported
Prednisone	S	Oral	Unk		Not Reported
Prednisone	S		Unk		Not Reported
Alendronate Sodium	S	Oral	Unk		Not Reported
Diclofenac Sodium	S		Unk		Not Reported
Hydroxychloroquine	S		Unk		Not Reported
Methotrexate Sodium	S		Unk		Not Reported
Methotrexate	S	Intra-arterial	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18277066	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017835		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Q.I.W		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Q.Wk.		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18282999	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017753			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect	Acetaminophen			S	Unknown	Unk		Apotex

Decreased	Hydroxychloroquine	S	Unknown	Unk		Apotex
	Methotrexate	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Cimzia	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Propofol	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18290269	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1079812			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Sulfate Tablets, Usp			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18294459	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP017931			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	300 Milligram, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Apotex
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18307139	NON-EXPEDITED			US-ADVANZ PHARMA-202009008715			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Conjunctival Discolouration; Hot Flush; Migraine; Night Sweats; Photosensitivity Reaction	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg, 1 In 14 D (40 Mg/ 0.4ml)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18308111	EXPEDITED (15-DAY)		OT	NVSC2020ES258432		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acanthosis; Acute Generalised Exanthematous Pustulosis; Eczema; Erythema; Extravasation Blood; Off Label Use; Parakeratosis; Product Use In Unapproved Indication; Purpura; Pustule; Rash Erythematous; Rash Pruritic; Skin Oedema	Hydroxychloroquine			S	Unknown	400 Mg, Bid (Day 1)		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Lopinavir/Ritonavir			S	Unknown	200 Mg/50 Mg, Bid		Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Teicoplanin			S	Unknown	Unk		Not Reported
	Teicoplanin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18317572	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2020-048486		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Covid-19; Off Label Use; Pancytopenia	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Linezolid			S	Intravenous (not otherwise specified)	600 Milligram, Two Times A Day (1200 Milligram, Once Aday)		Aurobindo

	Meropenem	S	Intravenous (not otherwise specified)	3 Gram, Once A Day	Aurobindo
	Mycophenolate	S	Unknown	1 Gram,Day 0 And Day 4, Reduced To 500 Mg/12 Hours,	Not Reported
	Paracetamol	S	Unknown	1 Gram	Aurobindo
	Basiliximab	S	Unknown	Unk,Day 0 And Day 4	Not Reported
	Prednisone	S	Unknown	20 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day (400 Milligram, Once A Day)	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Two Times A Day (800 Milligram, Once A Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18326753	EXPEDITED (15-DAY)		OT	BR-LUPIN PHARMACEUTICALS INC.-2020-06536		28 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Oseltamivir Phosphate			S	Unknown	75 Milligram, Bid		Lupin
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Unk		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Heparin			S	Unknown	40 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18326802	EXPEDITED (15-DAY)		OT	BR-LUPIN PHARMACEUTICALS INC.-2020-06749			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth	Azithromycin			S	Transplacental	500 Milligram, Qd		Lupin

Weight Baby; Premature Baby	Oseltamivir Phosphate		S	Transplacental	75 Milligram, Bid	Lupin
	Ceftriaxone		S	Transplacental	2 Gram, Unk	Lupin
	Hydroxychloroquine		S	Transplacental	400 Milligram, Bid	Lupin
	Heparin		S	Transplacental	40 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18326889	EXPEDITED (15-DAY)		OT	BR-LUPIN PHARMACEUTICALS INC.-2020-06534		34 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Ceftriaxone			S	Unknown	2 Gram, Qd		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Vancomycin			S	Unknown	1 Gram, Bid		Lupin
	Oseltamivir			S	Unknown	75 Milligram, Bid		Lupin
	Enoxaparin			C	Unknown	Initially With 40 Mg Daily, With Increments Up To 80 Mg/Day		Not Reported
	Enoxaparin			C	Unknown	80 Milligram, Qd		Not Reported
	Meropenem			C	Unknown	500 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18326959	EXPEDITED (15-DAY)		OT	BR-LUPIN PHARMACEUTICALS INC.-2020-06533		25 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydrocortisone			S	Unknown	2 Gram, Unk		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram Bid At Initiation		Lupin
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Oseltamivir Phosphate			S	Unknown	Unk		Lupin

	Ceftriaxone		S	Unknown	Unk	Lupin
	Vancomycin		S	Unknown	1 Gram, Bid	Lupin
	Azithromycin		S	Unknown	Unk	Lupin
	Meropenem		S	Unknown	500 Milligram, Tid	Not Reported
	Enoxaparin		S	Unknown	Unk	Not Reported
	Polymyxin B		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327003	EXPEDITED (15-DAY)		HO, OT	BR-LUPIN PHARMACEUTICALS INC.-2020-06792			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atelectasis Neonatal; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydrocortisone			S	Transplacental	2 Gram, Unk		Lupin
	Hydroxychloroquine			S	Transplacental	400 Milligram Bid At Initiation		Lupin
	Hydroxychloroquine			S	Transplacental	400 Milligram, Qd		Lupin
	Oseltamivir Phosphate			S	Transplacental	Unk		Lupin
	Ceftriaxone			S	Transplacental	Unk		Lupin
	Azithromycin			S	Transplacental	Unk		Lupin
	Enoxaparin			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327038	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2020SP007850		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Oseltamivir			S	Unknown	Unk		Strides
	Azithromycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327039	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2020SP010651		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Oseltamivir			S	Unknown	Unk		Strides
	Oseltamivir			S				Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Betamethasone			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327136	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2020372152		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Thrombocytopenia Neonatal	Methotrexate Sodium			S	Transplacental	Unk		Pfizer
	Quensyl			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327247	EXPEDITED (15-DAY)		HO, OT	IR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-262309		64 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Off Label Use	Irinotecan			S	Unknown	Unk		Sun
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	200 Mg Gavage Twice Daily		Ipca
	Lopinavir/Ritonavir			S	Unknown	400/100 Mg Gavage Twice		Not Reported

					Daily				
	Calcium Folinat		S	Unknown	Unk				Not Reported
	5-Fluorouracil		S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327298	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3580951-00		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Naprosyn			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported

	Omeprazole	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Ketoprofen	C			Not Reported
	Losec	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327767	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP018646		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Azathioprine			S	Unknown	Unk		Apotex
	Bromocriptine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Apotex
	Doxycycline			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Milligram, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Tenoxicam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Mercaptopurine			S	Unknown	Unk		Not Reported
	Pamidronate Disodium			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Mercaptopurine			C	Unknown	Unk		Not Reported

	Methylprednisolone		C	Unknown	Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327857	NON-EXPEDITED			PL-LUPIN PHARMACEUTICALS INC.-2020-04482		65 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Doxycycline			S	Unknown	100 Milligram, Qd		Novel Labs
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Methotrexate			S	Unknown	10 Milligram, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327900	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06622		48 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Psoriasis	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Metformin			S	Unknown	1000 Milligram, Bid		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Budesonide			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Ipratropium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327902	EXPEDITED (15-DAY)		OT	CH-LUPIN PHARMACEUTICALS INC.-2020-06579		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticaria	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk		Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk		Not Reported

	Thymosin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327968	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-203383		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Methotrexate			S	Unknown			Accord
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Rectal	2 Every 1 Days		Not Reported
	Xeljanz			C	Oral	2 Every 1 Days		Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			S	Unknown	1 Every 1 Days		Accord
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Methotrexate			S	Unknown			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18328037	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18328044	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202009008889			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Butterfly Rash; Pain; Periorbital Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk (Plaquenil)		Concordia
	Hydroxychloroquine			S	Unknown	Unk (Plaquenil)		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	(40 Mg,1 In 14 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18328361	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-262150		25 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Hydrocortisone			S	Unknown	2 Gram		Ranbaxy
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Ipca
	Oseltamivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18328363	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-262143		28 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Unknown	500 Milligram, Daily		Sun
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Oseltamivir			S	Unknown	75 Milligram, Bid		Not Reported
	Heparin			S	Unknown	40 International Unit, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18328455	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-262155			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Transplacental			Sun
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Transplacental	400 Milligram, Daily		Ipca
	Hydrocortisone			S	Transplacental	2 Gram		Ranbaxy
	Oseltamivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18328700	EXPEDITED (15-DAY)		OT	CA-ACCORD-203020		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood	Atorvastatin/Atorvastatin Calcium			S	Unknown	1 Every 1 Days		Not Reported

Glucose Abnormal; Cataract; Dizziness; Ear Discomfort; Erythema; Fatigue; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Muscle Spasms; Nausea; Rheumatoid Arthritis; Vomiting	Bisoprolol	S	Unknown	2 Every 1 Days	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sandostatin	S	Intramuscular	1 Every 1 Months	Not Reported
	Dapagliflozin	C	Unknown	1 Every 1 Days	Not Reported
	Sandostatin	S	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18328952	EXPEDITED (15-DAY)		OT	CA-ACCORD-203345			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Days		Accord
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks		Not Reported
	Leflunomide			S	Oral	1 Every 1 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 6 Weeks		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Days		Accord
	Methotrexate			S	Unknown	1 Every 1 Days		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329013	EXPEDITED (15-DAY)		OT	CA-ACCORD-203270		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastroenteritis; Hepatitis; Nausea	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Hydroxychloroquine			S	Unknown	1 Every 1 Days		Not Reported
	Enbrel			C	Unknown	1 Every 1 Weeks		Not Reported
	Humira			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329030	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027357			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			S	Unknown	325.0 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown	20.0 Mg, 1 Every 1 Day		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50.0 Mg, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, 2 Every 1 Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000.0 Mg		Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen;Codeine			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported

	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25.0 Milligram, 1 Every 1 Week	Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329033	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-077970		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Lyrica			S	Unknown	150 Milligram		Not Reported
	Methotrexate			S	Unknown	366 Dosage Form		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	350 Milligram		Not Reported
	Esomeprazole			C	Unknown	40 Milligram, Qd		Not Reported
	Esomeprazole			C	Unknown	40 Unk		Not Reported
	Lumigan Rc			C	Unknown	Unk Unk, Qd		Not Reported
	Sulfasalazine			C	Unknown	1000 Milligram, Bid		Not Reported
	Trazodone			C	Unknown	200 Milligram, Qd		Not Reported
	Tylenol			C	Unknown	3000 Milligram		Not Reported
	Tylenol Extra Strength			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk Unk, Qd		Not Reported
	Wellbutrin			C	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329038	EXPEDITED (15-DAY)		OT	CA-ACCORD-203320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S		1 Every 1 Days		Accord
	Hydroxychloroquine			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329039	EXPEDITED (15-DAY)		OT	CA-ACCORD-203287		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Accord
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329046	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-203380			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Methotrexate		S	Subcutaneous	1 Every 1 Weeks	Accord
	Cefazolin		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Leflunomide		S	Oral		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown	2 Every 1 Days	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Naproxen		C	Unknown		Not Reported
	Arava		C	Unknown		Not Reported
	Viread		C	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported
	Leflunomide		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329052	EXPEDITED (15-DAY)		OT	CA-ACCORD-203288		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Accord
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329053	EXPEDITED (15-DAY)		OT	CA-ACCORD-203317		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Arava			S				Not Reported
	Actemra			S	Intravenous bolus			Not Reported
	Apo-Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral	1 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip	2 Every 1 Days		Not Reported
	Rituximab			S	Intravenous drip	2 Every 1 Days		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib			S		2 Every 1 Days		Not Reported
	Xeljanz			S				Not Reported

	Prednisone		S	Oral	1 Every 1 Days	Not Reported
	Rituxan		S	Intravenous drip	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329060	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027365			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	10.0 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5.0 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329065	EXPEDITED (15-DAY)		OT	TR-ACCORD-203047		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Hydroxychloroquine			S				Not Reported
	Oseltamivir/Oseltamivir Phosphate			S				Not Reported
	Azithromycin			S				Not Reported
	Hydrochlorothiazide/Irbesartan			C				Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329089	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027422			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituximab (Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329155	EXPEDITED (15-DAY)		HO	CA-CELLTRION INC.-2020CA027402			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 12 Hours		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported

Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	680 Milligram	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every 1 Months	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, 1 Every 1 Weeks	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, 1 Every 1 Weeks	Not Reported
	Codeine Sulfate	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Weeks	Not Reported
	Enbrel	S	Unknown	50 Milligram, 1 Every 1 Weeks	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 1 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Weeks	Not Reported
	Myochrysine	S	Parenteral	50 Milligram, 1 Every 1 Months	Not Reported

	Orencia	S	Unknown	780 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown	780 Milligram, 1 Every 1 Weeks	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	388 Milligram	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Weeks	Not Reported
	Prednisone	C	Unknown	10 Milligram, 1 Every 1 Days	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329160	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027397			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis	Rituximab (Unknown)			S	Intravenous drip	1000.0 Milligram		Not Reported
	Enbrel			S	Unknown	25.0 Milligram,2 Every 1 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300.0 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329277	EXPEDITED (15-DAY)		OT	CA-ACCORD-203265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord

Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Hydroxychloroquine		S		1 Every 1 Days	Not Reported
	Gold		S			Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sodium Aurothiomalate		S			Not Reported
	Xeljanz		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329305	EXPEDITED (15-DAY)		OT	CA-ACCORD-203273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Accord
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	1 Every 1 Days		Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329309	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027060			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg		Not Reported
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329310	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027051			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329315	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027109			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329316	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027071			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329348	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027208			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance;	Rituximab (Unknown)			S	Intravenous (not			Not Reported

Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased				otherwise specified)	
	Azathioprine		S	Unknown	Not Reported
	Ciclosporin		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Mycophenolate Mofetil		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329349	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027469			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Rituximab (Unknown)			S	Intravenous drip			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329350	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2020CA027265			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug	Rituximab (Unknown)			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Weeks	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Viread	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329434	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027543			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituximab (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329451	EXPEDITED (15-DAY)		OT	MA-LUPIN PHARMACEUTICALS INC.-2020-06589		49 YR	Female	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329452	EXPEDITED (15-DAY)		OT	MA-LUPIN PHARMACEUTICALS INC.-2020-06591		70 YR	Male	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329456	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-06581		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Hydroxychloroquine			S				Lupin

	Lopinavir/Ritonavir	C	Oral	400/100 Mg, Bid	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	10 Milligram, Unk	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	5 Milligram, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329462	EXPEDITED (15-DAY)		OT	MA-LUPIN PHARMACEUTICALS INC.-2020-06588		76 YR	Unknown	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329476	EXPEDITED (15-DAY)		OT	MA-LUPIN PHARMACEUTICALS INC.-2020-06590		82 YR	Female	MAR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Azithromycin			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329565	NON-EXPEDITED			US-PFIZER INC-2020375640		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Xeljanz			S		5 Mg		Pfizer
	Diclofenac			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329672	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027528			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329930	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-06596		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Methylprednisolone			S	Intravenous (not otherwise specified)	1 Milligram/Kilogram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Tocilizumab			C	Unknown	400 Milligram		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330026	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA027666			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride;Perphenazine			S	Unknown			Not Reported
	Amitriptyline Hydrochloride;Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Diclo [Diclofenac Sodium]			S	Unknown			Not Reported
	Apo-Diclofenac			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S				Not Reported
	Diclofenac			S	Unknown			Not Reported

Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Weeks	Not Reported
Etanercept	S	Unknown		Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Misoprostol	S	Unknown		Not Reported
Naprosyn [Naproxen]	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Nifedipine	S	Unknown		Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750 Milligram, 1 Every 1 Weeks	Not Reported
Prednisone	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Winpred	S	Unknown		Not Reported
Xeljanz	S	Oral	1 Dosage Form, 2 Every 1 Days	Not Reported

	Tofacitinib			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330166	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2019432051		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Ineffective	Sulfasalazine			S		1500 Mg, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330232	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020182501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Glaxosmithkline
	Cortisone Acetate			S	Topical	25 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	40 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Once Daily (Qd)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Tocilizumab	S	Topical	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Actemra	S	Topical	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330355	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-078122		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb

Increased; C-Reactive Protein Increased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330364	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1081551		37 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Failure; Off Label Use	Azithromycin			S		250 Mg, Qd		Mylan
	Methylprednisolone			S		60 Mg, Qd		Mylan
	Kaletra			S		400/100 Mg/12 H		Mylan
	Dolquine			S		200 Mg, Q12h		Mylan
	Simvastatine			C	Oral	20 Mg		Mylan
	Omeprazol /00661201/			C	Oral	20 Mg		Mylan

Hidroferol	C	Unk Unk, Qm	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330420	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2020-06584		62 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid (On Day 1)		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid (From Day 2-4)		Lupin
	Azithromycin			S	Unknown	500 Milligram, Qd (On Day 1)		Lupin
	Azithromycin			S	Unknown	250 Milligram, Qd (From Day 2-4)		Lupin
	Oseltamivir			S	Unknown	75 Milligram, Bid (For 5 Days)		Lupin
	Enoxaparin			C	Unknown	40 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330458	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1081719		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Oral	10 Mg, Qd		Mylan
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832556		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition	Prednisone			S	Oral	50 Milligram Daily;		Actavis
	Prednisone			S	Oral	20 Milligram Daily;		Actavis

Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Rituximab	S	Intravenous drip	2000 Milligram Daily;		Not Reported
	Arava	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous drip	2000 Milligram Daily;		Not Reported
	Rituxan	S	Intravenous drip	2 Gram Daily;		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Tofacitinib Citrate	S	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330561	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832555		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown	9 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Infliximab	S	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Desoximetasone	C			Not Reported

	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown	10 Milligram Daily;	Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Gabapentin	C	Unknown	1800 Milligram Daily;	Not Reported
	Paracetamol	C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330564	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1832893		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Diclofenac			S	Unknown			Actavis
	Prednisone			S	Oral			Actavis
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	20 Milligram Daily;		Not Reported

Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram Daily;		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral			Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;		Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;		Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;		Not Reported
Topicort	S	Cutaneous			Not Reported
Sulfathalidine	S	Oral	2000 Milligram Daily;		Not Reported
Sulfathalidine	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330605	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06592		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Prednisone			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330670	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06595		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Hydroxychloroquine		S	Unknown	Unk	Lupin
	Azithromycin		S	Unknown	Unk	Lupin
	Ceftriaxone		S	Unknown	Unk	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330671	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06594		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Cefepime			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330672	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-06593		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330674	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020157854		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Gold	S	Other	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk		Not Reported
Remicade	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330677	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP018615			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330680	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2020-06580		47 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticarial Vasculitis	Ceftriaxone			S	Unknown	Unk		Lupin

	Hydroxychloroquine			S	Unknown	Unk			Lupin
	Lopinavir/Ritonavir			C	Unknown	Unk			Not Reported
	Enoxaparin			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18330814	EXPEDITED (15-DAY)		HO	TR-LUPIN PHARMACEUTICALS INC.-2020-06587		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Urticaria	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Irbesartan/Hydrochlorothiazide			C	Intracardiac	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331007	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1083011		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Off Label Use; Tachyarrhythmia	Azithromycin			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Tocilizumab			S	Unknown	400 Milligram		Mylan
	Immunoglobulin /00025201/			C	Intravenous (not otherwise specified)	Day 6-10		Mylan
	Ibrutinib			C	Unknown	140 Milligram, Qd		Mylan
	Ibrutinib			C	Unknown	420 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331051	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1833135		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Leflunomide	S	Oral	20 Milligram Daily;	Barr
	Actemra	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram Daily;	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methylprednisolone Acetate	C			Not Reported
	Prednisone	C			Not Reported
	Sulfasalazine	C	Oral	1 Gram Daily;	Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331052	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1833131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Acetaminophen/Caffeine Citrate/Codeine Phosphate	C	Unknown		Not Reported
	Baclofen	C	Unknown	20 Milligram Daily;	Not Reported
	Calcium Gluconate	C	Unknown		Not Reported
	Calcium Gluconate	C	Unknown		Not Reported
	Dorzolamide Hydrochloride /Timolol Maleate	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Estradiol	C	Unknown	1.8 Percent Daily;	Not Reported
	Estrogel	C	Unknown	1.8 Percent Daily;	Not Reported
	Furosemide	C	Unknown	40 Milligram Daily;	Not Reported
	Gravol	C			Not Reported
	Levaquin	C	Unknown	500 Milligram Daily;	Not Reported
	Morphine	C			Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram Daily;	Not Reported
	Valsartan	C	Unknown	320 Milligram Daily;	Not Reported

	Xalatan	C	Ophthalmic	50 Milligram Daily;		Not Reported
	Zingiber Officinale	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331054	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832956		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C				Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331166	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1833128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331175	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020375849		13 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Decreased; Blood Alkaline Phosphatase Increased; Blood Creatinine Decreased; C-Reactive Protein Increased; Haemoglobin Decreased; Hla-B*27 Positive; Swollen Joint Count; Toxicity To Various Agents; White Blood Cell Count Increased	Methotrexate			S		7.5 Mg		Pfizer
	Sulfasalazine			S		500 Mg		Pfizer
	Hydroxychloroquine			S		60 Mg		Not Reported
	Enbrel			C	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331190	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1833137		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Subcutaneous	Barr
	Abatacept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331266	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200943137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Remicade			S	Intravenous (not			Not Reported

Intolerance; Nausea			otherwise specified)	
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Intramuscular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331369	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1833153			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr

Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331370	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832951		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331372	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1832746		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Orencia		S	Unknown	Not Reported
	Orencia		S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1833160		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

	Prednisone		C	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331475	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1833144		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331489	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1832546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331503	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200944443			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tuberculosis	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331507	EXPEDITED (15-DAY)		HO	CH-ANIPHARMA-2020-CH-000032		30 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Pyrexia; Urogenital Infection Bacterial	Atacand			S	Oral			Ani
	Myfortic			S	Unknown	360 Mg-0-540 Mg		Not Reported
	Prednisone			S	Unknown	7.5 Mg Qam / Dose Text: Increased		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sortis			S	Unknown	10 Mg Daily		Not Reported
	Indapamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331525	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200944430		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Arava			S	Unknown			Not Reported

Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Arava	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Acetaminophen W/Oxycodone	C		2 Dosage Forms	Not Reported
	Asa	C			Not Reported
	Bisoprolol	C			Not Reported
	D-Alpha Tocopherol	C			Not Reported
	Endocet	C	Oral		Not Reported
	Folic Acid	C			Not Reported
	Indomethacin /00003801/	C			Not Reported
	Macrogol	C			Not Reported
	Metoprolol	C			Not Reported
	Naproxen Sodium	C			Not Reported
	Omega-3 /01866101/	C	Oral		Not Reported
	Pennsaid	C	Topical		Not Reported
	Vitamin B 12	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331581	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2020376535		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Thrombocytopenia	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Quensyl			S	Unknown	Unk		Not Reported